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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.

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

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1238

[No. 2023–N–4]

Orders: Reporting by Regulated Entities of Stress Testing Results as of December 31, 2022; Summary Instructions and Guidance

AGENCY: Federal Housing Finance Agency.

ACTION: Orders.

SUMMARY: In this document, the Federal Housing Finance Agency (FHFA) provides notice that it issued Orders, dated March 7, 2023, with respect to stress test reporting as of December 31, 2022, under section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), as amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA). Summary Instructions and Guidance accompanied the Orders to provide testing scenarios.

DATES: Each Order is applicable March 7, 2023.

FOR FURTHER INFORMATION CONTACT: John Williams, Associate Director, Office of Capital Policy, (202) 649–3159, *John.Williams@fha.gov;* Sara L. Todd, Assistant General Counsel, Office of General Counsel, (202) 649–3527, *Sara.Todd@fhfa.gov;* or James Jordan, Deputy General Counsel, Office of General Counsel, (202) 649–3570, *James.Jordan@fhfa.gov.* For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is responsible for ensuring that the regulated entities operate in a safe and sound manner, including the maintenance of adequate capital and internal controls, that their operations and activities foster liquid, efficient, competitive, and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See* 12 U.S.C. 4513. These Orders are being issued under 12 U.S.C. 4516(a), which authorizes the Director of FHFA to require by Order that the regulated entities submit regular or special reports to FHFA and establishes remedies and procedures for failing to make reports required by Order. The Orders, through the accompanying Summary Instructions and Guidance, prescribe for the regulated entities the scenarios to be used for stress testing. The Summary Instructions and Guidance also provides to the regulated entities advice concerning the content and format of reports required by the Orders and the rule.

II. Orders, Summary Instructions and Guidance

For the convenience of the affected parties and the public, the text of the Orders follows below in its entirety. The Orders and Summary Instructions and Guidance are also available for public inspection and copying at the Federal Housing Finance Agency's Freedom of Information Act (FOIA) Reading Room at *https://www.fhfa.gov/AboutUs/FOIAPrivacy/Pages/Reading-Room.aspx* by clicking on ''Click here to view Orders'' under the Final Opinions and Orders heading. You may also access these documents at *http://www.fhfa.gov/SupervisionRegulation/DoddFrankActStressTests.*

The text of the Orders is as follows:

Federal Housing Finance Agency

Order Nos. 2023–OR–FNMA–1 and 2023–OR–FHLMC–1

Reporting by Regulated Entities of Stress Testing Results as of December 31, 2022

Whereas, section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''), as amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (''EGRRCPA'') requires certain financial companies with total consolidated assets of more than $250 billion, and which are regulated by a primary Federal financial regulatory agency, to conduct periodic stress tests to determine whether the companies have the capital necessary to absorb losses as a result of severely adverse economic conditions;

Whereas, FHFA's rule implementing section 165(i)(2) of the Dodd-Frank Act, as amended by section 401 of EGRRCPA is codified as 12 CFR 1238 and requires that ''[e]ach Enterprise must file a report in the manner and form established by FHFA.'' 12 CFR 1238.5(b);

Whereas, The Board of Governors of the Federal Reserve System issued stress testing scenarios on February 9, 2023; and

Whereas, section 1314 of the Safety and Soundness Act, 12 U.S.C. 4514(a) authorizes the Director of FHFA to require regulated entities, by general or specific order, to submit such reports on their management, activities, and operation as the Director considers appropriate.

Now therefore, it is hereby Ordered as follows:

Each Enterprise shall report to FHFA and to the Board of Governors of the Federal Reserve System the results of the stress testing as required by 12 CFR 1238, in the form and with the content described therein and in the Summary Instructions and Guidance, with Appendices 1 through 7 thereto, accompanying this Order and dated March 7, 2023.

It Is So Ordered, this the 7th day of March, 2023.

This Order is effective immediately.

Signed at Washington, DC, this 7th day of March, 2023.

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

[FR Doc. 2023–04980 Filed 3–9–23; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0423; Project Identifier AD–2022–01525–E; Amendment 39–22366; AD 2023–04–19]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain General Electric Company (GE) GE90–110B1 and GE90–115B model turbofan engines. This AD was prompted by a manufacturer investigation which discovered that florescent penetrant inspections (FPI) were not performed on the dovetail pressure face of certain high-pressure compressor (HPC) rotor spools at overhaul. This AD requires FPI of the affected HPC rotor stage 7–9 spool and, depending on the results of the inspection, replacement with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 27, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 27, 2023.

The FAA must receive comments on this AD by April 24, 2023.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2023–0423; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference

- For service information identified in this final rule, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2023–0423.

FOR FURTHER INFORMATION CONTACT: Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: *Stephen.L.Elwin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA received a report that a GE overhaul shop internal investigation found that several HPC rotor stage 7–9 spools were shipped to operators prior to a final FPI being performed on the dovetail pressure face. A final FPI is performed to confirm that any linear indications have been removed, as indications on the HPC rotor stage 7–9 spool may potentially propagate and eventually lead to failure of the HPC rotor stage 7–9 spool. This condition, if not addressed, could result in an in-flight shutdown, damage to the engine, and damage to the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE GE90–100 Service Bulletin 72–0905 R00, dated July 25, 2022. This service information specifies procedures for performing a piece-part inspection of the affected HPC rotor stage 7–9 spools. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

AD Requirements

This AD requires, at the next shop visit after the effective date of this AD, performing an FPI of each affected HPC rotor stage 7–9 spool and, depending on the results of the inspection, replacement with a part eligible for installation.

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.

The FAA has found the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from any U.S. operator. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason(s), 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.

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 ''FAA–2023–0423 Project Identifier AD–2022–01525–E'' 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 *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 Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. 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 0 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Perform an FPI of the HPC rotor stage 7–9 spool.	5 work-hours × $85 per hour = $425	$0	$425	$0

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace the HPC rotor stage 7–9 spool	40 work-hours × $85 per hour = $3,400	$1,183,200	$1,186,600

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:

2023–04–19 General Electric Company: Amendment 39–22366; Docket No. FAA–2023–0423; Project Identifier AD–2022–01525–E.

(a) Effective Date

This airworthiness directive (AD) is effective March 27, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) GE90–110B1 and GE90–115B model turbofan engines with an installed high-pressure compressor (HPC) rotor stage 7–9 spool with part number (P/N) 2032M23G01, P/N 2032M23G02, P/N 2676M00G01, or P/N 2676M00G02, and a serial number listed in paragraph 4., Appendix—A, Table 1 of GE GE90–100 Service Bulletin (SB) 72–0905 R00, dated July 25, 2022 (GE SB 72–0905).

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by a manufacturer investigation which revealed that florescent penetrant inspections (FPI) were not performed on the dovetail pressure face of certain HPC rotor stage 7–9 spools at overhaul. The FAA is issuing this AD to prevent the failure of the HPC rotor stage 7–9 spool. The unsafe condition, if not addressed, could result in an in-flight shutdown, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) At the next engine shop visit after the effective date of this AD, perform an FPI of the dovetail pressure face of the affected HPC rotor stage 7–9 spool in accordance with the

Accomplishment Instructions, paragraph 3.A.(1)(a) of GE SB 72–0905.

(2) If, during the FPI required by paragraph (g)(1) of this AD, the HPC rotor stage 7–9 spool does not meet the part serviceability criteria in the Accomplishment Instructions, paragraph 3.A.(1)(a) of GE SB 72–0905, before further flight, replace the compressor rotor stage 7–9 spool with a part eligible for installation.

(h) Definition

For the purpose of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving separation of pairs of major mating engine flanges, except for the following situations, which do not constitute an engine shop visit:

(i) Separation of engine flanges solely for the purposes of transportation of the engine without subsequent maintenance; or

(ii) Separation of engine flanges solely for the purpose of replacing the fan or propulsor without subsequent maintenance.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD and email it to: *ANE-AD-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.

(j) Related Information

For more information about this AD, contact Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: *Stephen.L.Elwin@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) GE GE90–100 Service Bulletin 72–0905 R00, dated July 25, 2022.

(ii) [Reserved]

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com;* website: *ge.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. 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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 25, 2023.

Christina Underwood,

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

[FR Doc. 2023–04869 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1058; Project Identifier AD–2022–00256–T; Amendment 39–22340; AD 2023–03–15]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–07–09, which applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. AD 2021–07–09 required repetitively inspecting all trim air diffuser ducts or sidewall riser duct assemblies (collectively referred to as TADDs) for damage, including repetitive structural inspections of the center fuel tanks for damage, and performing applicable on-condition actions. Since the FAA issued AD 2021–07–09, the agency has determined that the existing requirements do not adequately address the unsafe condition. This AD continues to require repetitive inspections of the TADDs for damage, with revised compliance times, and repair if applicable. This AD also requires repetitive replacement of the TADDs and removes the structural inspections of the center fuel tanks. This AD also prohibits the installation of affected parts. This AD removes certain airplanes from the applicability. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 14, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 14, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1058; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *myboeingfleet.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1058.

FOR FURTHER INFORMATION CONTACT: Nicole S. Tsang, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3959; email: *nicole.s.tsang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–07–09, Amendment 39–21486 (86 FR 17899, April 7, 2021) (AD 2021–07–09). AD 2021–07–09 applied to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. The NPRM published in the **Federal Register** on September 8, 2022 (87 FR 54919). The NPRM was prompted by reports of sealant deteriorating on the outside of the center wing fuel tank and analysis showing that sealant may deteriorate inside the tank due to excess heat from TADDs. The NPRM was also prompted by reports indicating that the high temperature composite material TADD failed. AD 2021–07–09 requires replacing original fiberglass fabric material with high temperature composite material TADDs, repetitively inspecting the TADDs for damage, and

as applicable inspecting the center wing fuel tank secondary fuel barrier coating and primary sealant for damage, and repairing damage. In the NPRM, the FAA proposed to continue to require repetitive inspections of the TADDs for damage, with revised compliance times, and repair if applicable. The NPRM also proposed to require repetitive replacement of the TADDs and remove the structural inspections of the center fuel tanks. In addition, this AD prohibits the installation of affected parts. The FAA is issuing this AD to address potential hot air leakage from original fiberglass fabric material or high temperature composite material TADD that can cause damage to the center wing fuel tank secondary fuel barrier coating and primary sealant, which can cause fuel leakage into an ignition zone, possibly resulting in a fire or explosion.

For information on the procedures and compliance times, see the service information at *regulations.gov* under Docket No. FAA–2022–1058.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from four commenters. Commenters included Air Line Pilots Association, International (ALPA) who supported the NPRM without change, and an individual whose comment is outside the scope of this rulemaking. The FAA received additional comments from Boeing and another commenter. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Clarification on Credit for Previous Actions

A commenter asked if an operator can claim full credit against the proposed AD if the operator with Group 2 airplanes performed Boeing Service Bulletin 747–21A2577–00 and conducted the TADD replacement associated with certain comments from AD 2021–07–09 in order to extend the inspection interval.

The FAA infers the commenter is referring to the FAA's response to a comment in AD 2021–07–09. That response states as follows:

After initial installation of high temperature TADDs, operators may avoid repeat inspections at 1,200 FH intervals by installing new high temperature TADDs at each 16,000 FH interval, without an alternative method of compliance (AMOC) or additional rulemaking, as long as required actions are completed at that interval.

The FAA infers the commenter is requesting the same allowance from the FAA's response to the comment in AD 2021–07–09 to replace the TADD in lieu of performing repetitive inspections of the TADD at 1,200-flight-hour intervals. The FAA provides the following clarifications of the AD requirements. This AD requires operators to perform repetitive inspection of the TADD, report any TADD damages to Boeing, and replace the TADD at 16,000-flight-hour intervals. This AD does not provide an option for a TADD to continue in service after 16,000 flight hours.

The proposed AD would have required Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 1, dated March 9, 2022. This AD has been revised to require Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023. However, paragraph (j) of this AD provides credit for actions done before the effective date of the AD using Boeing Alert Requirements Bulletin 747–21A2577 RB, dated February 18, 2020; or Revision 1, dated March 9, 2022.

Request for Change in Applicability

Boeing requested that the FAA revise paragraph (c), ''Applicability,'' of the proposed AD to remove the following Model 747 Large Cargo Freighters (LCF) airplanes: variable numbers RT631, RT743, RT876, and RT632. The listed LCF airplanes should not be applicable because the listed LCF airplanes do not have original fiberglass fabric material or high temperature composite material TADD.

The FAA agrees with the request for the reasons provided by the commenter. The FAA notes that paragraph 1.A., ''Effectivity,'' of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, specifically excludes line numbers 766, 778, 904, and 932 (variable numbers RT631, RT743, RT876, and RT632). The FAA revised paragraph (c) of this AD to limit the applicability to airplanes identified in Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023.

Request for Change to the Service Bulletins Cited

Boeing requested the FAA to reference Revision 2 instead of Revision 1 of Service Bulletin and Requirements Bulletin 747–21A2577. Revision 2 of this service information will address the issue of Appendix A and Appendix B not being in the RB.

The FAA agrees with Boeing's request. As stated previously, the FAA has revised this AD to require Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023. Revision 2 added the missing appendixes and introduces no other changes that affect compliance.

Conclusion

The FAA reviewed the relevant data, considered any 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 products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023. This service information specifies procedures for repetitive detailed inspections for damage of TADDs made of original fiberglass fabric material and high temperature composite material, repetitive replacement of TADDs, and repair of damaged TADDs. 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**.

Costs of Compliance

The FAA estimates that this AD affects 104 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained repetitive inspections (AD2021–07–09).	Up to 44 work-hours × $85 per hour = up to $3,740 per inspection cycle.	$0	Up to $3,740 per inspection cycle.	Up to $388,960 per inspection cycle.

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive TADD replacement.	Up to 49 work-hours × $85 per hour = $4,165 per replacement cycle.	Up to $12,000	Up to $16,165 per inspection cycle.	Up to $1,681,160 per replacement cycle.

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(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:

■ a. Removing Airworthiness Directive (AD) 2021–07–09, Amendment 39–21486 (86 FR 17899, April 7, 2021); and

■ b. Adding the following new AD:

2023–03–15 The Boeing Company: Amendment 39–22340; Docket No. FAA–2022–1058; Project Identifier AD–2022–00256–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 14, 2023.

(b) Affected ADs

This AD replaces AD 2021–07–09, Amendment 39–21486 (86 FR 17899, April 7, 2021) (AD 2021–07–09).

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023.

(d) Subject

Air Transport Association (ATA) of America Code: 21, Air conditioning.

(e) Unsafe Condition

This AD was prompted by reports of sealant deteriorating on the outside of the center wing fuel tank and analysis showing that sealant could deteriorate inside the fuel tank due to excess heat from trim air diffuser ducts or sidewall riser duct assemblies (collectively referred to as TADDs), and by the determination that existing requirements do not adequately address the unsafe condition. The FAA is issuing this AD to address potential hot air leakage from original fiberglass fabric material or high temperature composite material TADDs that can cause damage to the center wing fuel tank secondary fuel barrier coating and primary sealant, which can cause fuel leakage into an ignition zone, possibly resulting in a fire or explosion.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 747–21A2577, Revision 2, dated February 10, 2023, which is referred to in Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time column of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, uses the phrase ''the Revision 1 date of Requirements Bulletin 747–21A2577 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(i) Parts Installation Prohibition

As of the effective date of this AD, no person may install an original fiberglass fabric material TADD assembly, having a part number listed in Appendix A of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, on any airplane.

(j) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service

information identified in paragraph (j)(1) or (2) of this AD.

(1) Boeing Alert Requirements Bulletin 747–21A2577 RB, dated February 18, 2020, which was incorporated by reference in AD 2021–07–09.

(2) Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 1, dated March 9, 2022, which is not incorporated by reference in this AD.

(k) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2021–07–09 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023, that are required by paragraph (g) of this AD.

(l) Related Information

For more information about this AD, contact Nicole S. Tsang, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3959; email: *nicole.s.tsang@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 747–21A2577 RB, Revision 2, dated February 10, 2023.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 25, 2023.

Christina Underwood,

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

[FR Doc. 2023–04848 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1309; Project Identifier MCAI–2021–01288–T; Amendment 39–22221; AD 2022–22–06]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A310 series airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, 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 March 27, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 27, 2023.

The FAA must receive comments on this AD by April 24, 2023.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1309; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1309.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

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–2022–1309; Project Identifier MCAI–2021–01288–T'' 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 *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 final rule, 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 final rule. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0257, dated November 17, 2021 (EASA AD 2021–0257) (referred to after this as the MCAI), to correct an unsafe condition on all Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes. The MCAI states that the limit of validity (LOV) has been revised to be more restrictive, reflecting the engineering data that supports the structural maintenance program and that corresponds to the time period during which it is demonstrated that Widespread Fatigue Damage (WFD) will not occur.

EASA AD 2021–0257 specifies that it requires a task (limitation) related to the LOV already in Airbus A310 Airworthiness Limitations Section (ALS), Part 2, Damage Tolerant Airworthiness Limitation Items (DT–ALI), Revision 03, dated December 14, 2018, that is required by EASA AD 2019–0091, dated April 26, 2019 (which corresponds to FAA AD 2019–20–06, Amendment 39–19759 (84 FR 55859, October 18, 2019) (AD 2019–20–06)) (and is incorporated by reference in AD 2019–20–06), and that incorporation of EASA AD 2021–0257 invalidates (terminates) the prior LOV as specified in Airbus A310 Airworthiness Limitations Section (ALS), Part 2, Damage Tolerant Airworthiness Limitation Items (DT–ALI), Revision 03, dated December 14, 2018. This AD therefore terminates the limitations for the LOV, as required by paragraph (g) of AD 2019–20–06.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1309.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2021–0257. This service information specifies new or more restrictive airworthiness limitations for airplane LOVs. 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.

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 described above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2021–0257 described previously, as incorporated by reference. Any differences with EASA AD 2021–0257 are identified as exceptions in the regulatory text of this AD.

This AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (j)(1) of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2021–0257 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2021–0257 through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0257 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0257. Service information required by EASA AD 2021–0257 for compliance will be available at *regulations.gov* under Docket No. FAA–2022–1309 after this final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness

limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections or intervals) may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

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.

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason(s), 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.

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 the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. For any affected airplane that may be imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

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:

2022–22–06 Airbus SAS: Amendment 39–22221; Docket No. FAA–2022–1309; Project Identifier MCAI–2021–01288–T.

(a) Effective Date

This airworthiness directive (AD) is effective March 27, 2023.

(b) Affected ADs

This AD affects AD 2019–20–06, Amendment 39–19759 (84 FR 55859, October 18, 2019) (AD 2019–20–06).

(c) Applicability

This AD applies to all Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Revision of the Existing Maintenance or Inspection Program

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 2021–0257, dated November 17, 2021 (EASA AD 2021–0257).

(h) Exceptions to EASA AD 2021–0257

(1) Where paragraph (1) of EASA AD 2021–0254 specifies ''This AD invalidates the LOV [limit of validity] as specified in Airbus A310 ALS Part 2 Revision 03 [EASA AD 2019–0091],'' replace that text with ''This AD replaces the LOVs specified in paragraph 3.1 of Airbus A310 Airworthiness Limitations Section (ALS), Part 2, Damage Tolerant Airworthiness Limitation Items (DT–ALI), Revision 03, dated December 14, 2018, as required by FAA AD 2019–20–06.''

(2) Paragraph (2) of EASA AD 2021–0257 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The ''Remarks'' section of EASA AD 2021–0257 does not apply to this AD.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0257.

(j) Additional AD Provisions

The following provisions also apply to this AD.

(1) *Alternative Methods of Compliance (AMOCs):* 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 responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(l) 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 2021–0257, dated November 17, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0257, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 20, 2022.

Christina Underwood,

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

Editorial Note: This document was received for publication by the Office of the Federal Register on March 7, 2023.

[FR Doc. 2023–04941 Filed 3–9–23; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1244; Project Identifier MCAI–2022–00872–E; Amendment 39–22361; AD 2023–04–14]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–12–01, which applied to certain Rolls-Royce Deutschland Ltd. & Co KG (RRD) Trent XWB–75, Trent XWB–79, Trent XWB–79B, and Trent XWB–84 model turbofan engines. AD 2020–12–01 required initial and repetitive inspections of the low pressure compressor (LPC) outlet guide vane (OGV) outer mount ring assembly and, depending on the results of the inspections, possible replacement of the LPC OGV outer mount ring assembly. Since the FAA issued AD 2020–12–01, the FAA determined that these inspections are also necessary for RRD Trent XWB–97 model turbofan engines. This AD was prompted by analysis by the manufacturer of the LPC OGV assembly and LPC OGV outer mount ring assembly which predicted that when the front engine mount is in the fail-safe condition, the most highly stressed LPC OGV assembly has a life that could be substantially less than one shop visit interval. This AD requires initial and repetitive inspections of the LPC OGV outer mount ring assembly and, depending on the results of the inspections, replacement of the LPC OGV outer mount ring assembly, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference (IBR). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 14, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 14, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1244; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material that is proposed for IBR in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2022–1244.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–12–01, Amendment 39–21135 (85 FR 34959, June 8, 2020) (AD 2020–12–01). AD 2020–12–01 applied to certain RRD Trent XWB–75, Trent XWB–79, Trent XWB–79B, and Trent XWB–84 model turbofan engines. AD 2020–12–01 required initial and repetitive inspections of the LPC OGV outer mount ring assembly and, depending on the results of the inspections, possible replacement of the OGV outer mount

ring assembly. The FAA issued AD 2020–12–01 to prevent failure of the front engine mount support structure.

The NPRM published in the **Federal Register** on September 30, 2022 (87 FR 59347). The NPRM was prompted by EASA AD 2022–0129, dated June 30, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0129) (referred to after this as ''the MCAI''). The MCAI superseded EASA AD 2019–0234, dated September 19, 2019 (EASA AD 2019–0234). EASA AD 2019–0234 specified that operators perform repetitive inspections (on-wing or in-shop) of the OGV outer mount ring assembly lug fillet area in accordance with RRD Alert Non-Modification Service Bulletin (NMSB) Trent XWB 72–AK188, Initial Issue, dated August 13, 2019. The manufacturer subsequently revised the NMSB and determined that the inspections of the LPC OGV outer mount ring assembly are also necessary for RRD Trent XWB–97 model turbofan engines. In addition, manufacturer analysis indicated that the on-wing inspections, previously specified in RRD NMSB Trent XWB 72–AK188, original issue, dated August 13, 2019, could be discontinued, and the interval of the in-shop inspection could coincide with a qualified shop visit, as outlined in RRD NMSB Trent XWB 72–AK188, Revision 3, dated May 9, 2022. As a result, EASA issued EASA AD 2022–0129 to discontinue the on-wing inspections, allow the in-shop inspection interval to be adjusted, and expand the applicability to include Trent XWB–97 model turbofan engines. You may examine issued EASA AD 2022–0129 in the AD docket at *regulations.gov* under Docket No. FAA–2022–1244.

In the NPRM, the FAA proposed to require initial and repetitive inspections of the LPC OGV outer mount ring assembly and, depending on the results of the inspections, replacement of the LPC OGV outer mount ring assembly, as specified in EASA AD 2022–0129. The FAA is issuing this AD to prevent failure of the front engine mount support structure.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters. The commenters were Air Line Pilots Association, International (ALPA), Delta Air Lines, Inc, (DAL), and Rolls-Royce, plc. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

ALPA supported the NPRM without change.

Request To Remove Proposed Paragraph (j), Special Flight Permit

DAL requested that the FAA remove the Special Flight Permit paragraph, as proposed in the NPRM. DAL explained that EASA AD 2022–0129 specifies that all inspections and corrective actions occur during a qualified engine shop visit. DAL stated that an affected engine cannot be returned to service until all inspections and corrective actions are complied with and, therefore, the special flight permit prohibition proposed in the NPRM is not necessary.

The FAA agrees and has omitted the proposed Special Flight Permit paragraph from this final rule.

Request To Revise References to LPC OGV Outer Mount Ring Assembly

Rolls-Royce, plc. commented that both the Background section and paragraph (e), Unsafe Condition, of the proposed AD refer to ''the most highly stressed LPC OGV outer mount ring assembly.'' The commenter stated that both paragraphs should be revised to instead refer to ''the most highly stressed LPC Outlet Guide Vane'' in order to correct the description of the affected part that has a life that could be substantially less than one shop visit.

In response to this comment, the FAA partially agrees with the request to correct the description of the affected part, and has updated this final rule by changing ''the most highly stressed LPC OGV outer mount ring assembly'' to ''the most highly stressed LPC OGV assembly'' in paragraph (e), Unsafe Condition, and in the preamble.

Request To Clarify Service Bulletin for Trent XWB–97 Model Turbofan Engines

Rolls-Royce, plc. noted that the proposed AD references RRD Alert NMSB Trent XWB 72–AK188, Revision 3, dated May 9, 2022, when referring to inspections of the LPC OGV on Trent XWB–97 model turbofan engines. However, Rolls-Royce, plc. stated inspections of the LPC OGV on Trent XWB–97 model turbofan engines are covered in RRD Alert NMSB Trent XWB 72–AK583, Initial Issue, dated May 9, 2022.

The FAA agrees and has updated the Actions Since AD 2020–12–01 Was Issued paragraph of the preamble to reference RRD Alert NMSB Trent XWB 72–AK583, Initial Issue, dated May 9, 2022, when referencing inspections of the LPC OGV for Trent XWB–97 model turbofan engines. The FAA also added RRD Alert NMSB Trent XWB 72–AK583, Initial Issue, dated May 9, 2022, to the Other Related Service Information paragraph of the preamble.

Conclusion

These products have been approved by the aviation authority of another country and are 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 referenced above. 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 products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022–0129. This EASA AD specifies instructions for performing fluorescent penetrant inspections (FPIs) of the LPC OGV outer mount ring assembly.

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 RRD Alert NMSB Trent XWB 72–AK188, Revision 3, dated May 9, 2022, and RRD Alert NMSB Trent XWB 72–AK583, Initial Issue, dated May 9, 2022. This service information specifies procedures for performing FPIs of the LPC OGV outer mount ring assembly.

Costs of Compliance

The FAA estimates that this AD affects 60 engines installed on airplanes of U.S. Registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
FPI the LPC OGV outer mount ring assembly	3 work-hours × $85 per hour = $255	$0	$255	$15,300

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair LPC OGV outer mount ring assembly	.5 work-hours × $85 per hour = $42.50	$0	$42.50
Replace the LPC OGV outer mount ring assembly	8 work-hours × $85 per hour = $680	2,418,121	2,418,801
Replace the OGV outer mount ring only	8 work-hours × $85 per hour = $680	894,319	894,999

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:

■ a. Removing Airworthiness Directive 2020–12–01, Amendment 39–21135 (85 FR 34959, June 8, 2020); and

■ b. Adding the following new airworthiness directive:

2023–04–14 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls Royce plc): Amendment 39–22361; Docket No. FAA–2022–1244; Project Identifier MCAI–2022–00872–E.

(a) Effective Date

This airworthiness directive (AD) is effective April 14, 2023.

(b) Affected ADs

This AD replaces AD 2020–12–01, Amendment 39–21135 (85 FR 34959, June 8, 2020) (AD 2020–12–01).

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd. & Co KG (RRD) Trent XWB–75, Trent XWB–79, Trent XWB–79B, Trent XWB–84, and Trent XWB–97 model turbofan engines as identified in European Union Aviation Safety Agency (EASA) AD 2022–0129, dated June 30, 2022. (EASA AD 2022–0129).

(d) Subject

Joint Aircraft Service Component (JASC) Code 7120, Engine Mount Sector.

(e) Unsafe Condition

This AD was prompted by analysis by the manufacturer of the low-pressure compressor (LPC) outlet guide vane (OGV) assembly and LPC OGV outer mount ring assembly. The analysis predicted that when the front engine mount is in the fail-safe condition, the most highly stressed LPC OGV assembly has a life that could be substantially less than one shop visit interval. The FAA is issuing this AD to prevent failure of the front engine mount support structure. The unsafe condition, if not addressed, could result in engine separation, reduced control of the airplane, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Perform all required actions within the compliance times specified in, and in accordance with, EASA AD 2022–0129.

(h) Exceptions to EASA AD 2022–0129

(1) Where EASA AD 2022–0129 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the Remarks paragraph of EASA AD 2022–0129.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0129 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly

to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD or email to: *ANE-AD-AMOC@faa.gov.* 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.

(k) Additional Information

(1) For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(2) For service information identified in this AD that is not incorporated by reference, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *rolls-royce.com/contact-us.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 AD 2022–0129, dated June 30, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0129, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 17, 2023.

Christina Underwood,

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

[FR Doc. 2023–04860 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0521; Project Identifier MCAI–2022–00273–T; Amendment 39–22187; AD 2022–20–03]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain MHI RJ Aviation ULC Model CL–600–2C10 (Regional Jet Series 700, 701 & 702); CL–600–2C11 (Regional Jet Series 550); CL–600–2D15 (Regional Jet Series 705); CL–600–2D24 (Regional Jet Series 900); and CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by laboratory tests that showed that the oxygen tubes of the crew oxygen system may be contaminated with lubricants, as a result of the manufacturing and cleaning procedures used. This AD requires cleaning and flushing the crew oxygen system. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 14, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 14, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–0521; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* website *mhirj.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–0521.

FOR FURTHER INFORMATION CONTACT: Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain MHI RJ Aviation ULC Model CL–600–2C10 (Regional Jet Series 700, 701 & 702); CL–600–2C11 (Regional Jet Series 550); CL–600–2D15 (Regional Jet Series 705); CL–600–2D24 (Regional Jet Series 900); and CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM published in the **Federal Register** on May 17, 2022 (87 FR 29841). The NPRM was prompted by AD CF–2022–06, dated February 28, 2022, issued by Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada (referred to after this as the MCAI). The MCAI states that laboratory tests showed that the oxygen tubes of the crew oxygen system may be contaminated with lubricants, as a result of the inadvertent use of a non-conforming aqueous degreasing process for oxygen line flushing and cleaning during the manufacturing process. If not corrected, lubricant remaining in oxygen lines could lead to a fire within the oxygen tubes or a health hazard related to the inhalation of lubricant fumes through the masks when masks are in use.

In the NPRM, the FAA proposed to require cleaning and flushing the crew oxygen system. The FAA is issuing this AD to address the contaminated oxygen tubes of the crew oxygen system, which could lead to a fire within the oxygen tubes, or a health hazard related to the inhalation of lubricant fumes when the masks are in use.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–0521.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from MHI RJ Aviation ULC. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Change MHI RJ Contact Information

MHI RJ Aviation ULC requested that the NPRM be revised to correct its contact information.

The FAA has included the correct contact information under **ADDRESSES** in this final rule and in paragraph (k)(3) of this AD.

Conclusion

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 referenced above. 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 this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed MHI RJ Service Bulletin 670BA–35–016, Revision B, dated December 17, 2021. This service information specifies procedures for low-pressure and high-pressure cleaning of the crew oxygen tubes. The tasks include cleaning the end fittings and threads, cleaning the inner wall of the tubes with solvent, and flushing the inner wall of the tubes with nitrogen.

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

Costs of Compliance

The FAA estimates that this AD would affect 34 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
51 work-hours × $85 per hour = $4,335	Up to $1,240	Up to $5,575	Up to $189,550.

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:

2022–20–03 MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22187; Docket No. FAA–2022–0521; Project Identifier MCAI–2022–00273–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 14, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) and CL–600–2C11 (Regional Jet Series 550) airplanes, serial numbers 10346 and 10347.

(2) Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15413 through 15484 inclusive.

(3) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, serial numbers 19049 through 19064 inclusive.

(4) Model CL–600–2C10, CL–600–2C11, CL–600–2D15, CL–600–2D24 and CL–600–2E25 airplanes equipped with tube part numbers installed after the dates indicated in Section 1.A.(2) of MHI RJ Service Bulletin (SB) 670BA–35–016, Revision B, dated December 17, 2021.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Unsafe Condition

This AD was prompted by laboratory tests that showed that the oxygen tubes of the crew oxygen system may be contaminated with lubricants, as a result of the manufacturing and cleaning procedures. The

FAA is proposing this AD to address the contaminated oxygen tubes of the crew oxygen system, which could lead to a fire within the oxygen tubes, or a health hazard related to the inhalation of lubricant fumes when the masks are in use.

(f) Compliance

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

(g) Requirements

Within 8,800 flight hours after the effective date of this AD, clean and flush the crew oxygen system, in accordance with the Accomplishment Instructions of MHI RJ Service Bulletin 670BA–35–016, Revision B, dated December 17, 2021.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by this AD, if those actions were performed before the effective date of this AD, using the service information identified in paragraph (h)(1) or (2) of this AD.

(1) MHI RJ Service Bulletin 670BA–35–016, dated February 26, 2021.

(2) MHI RJ Service Bulletin 670BA–35–016, Revision A, dated November 5, 2021.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or MHI RJ Aviation ULC's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to TCCA AD CF–2022–06, dated February 28, 2022, for related information. This TCCA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–0521.

(2) For more information about this AD, contact Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) MHI RJ Service Bulletin 670BA–35–016, Revision B, dated December 17, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* website *mhirj.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 13, 2022.

Christina Underwood,

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

Editorial Note: This document was received for publication by the Office of the Federal Register on March 7, 2023.

[FR Doc. 2023–04946 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0873; Project Identifier MCAI–2022–00060–T; Amendment 39–22183; AD 2022–19–14]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Embraer S.A. Model EMB–545 and EMB–550 airplanes. This AD was prompted by a report that there is a possibility of the shoulder belt getting stuck during flight due to a step between the divan shroud chamfer and the sideledge panel. This AD requires installing, on the right- and left-hand side divan, a protective fairing covering on the divan shroud and the sideledge panel, as specified in an Agência Nacional de Aviação Civil (ANAC) 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 April 14, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 14, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–0873; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference (IBR) in this AD, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br*; website *anac.gov.br/en/.* You may find this IBR material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2022–0873.

FOR FURTHER INFORMATION CONTACT: Ho-Joon Lim, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3405; email *ho-joon.lim@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Embraer S.A. Model

EMB–545 and EMB–550 airplanes. The NPRM published in the **Federal Register** on July 13, 2022 (87 FR 41629). The NPRM was prompted by AD 2021–11–01R1, issued by ANAC, which is the aviation authority for Brazil (referred to after this as the MCAI). The MCAI states that there is a possibility of the shoulder belt getting stuck during flight due to a step between the divan shroud chamfer and the sideledge panel. This set up may interfere with the correct kinematics of the shoulder belt during its retraction. This condition, if not addressed, could affect the shoulder belt release during turbulence or an emergency landing situation and result in injury to passengers and the flightcrew.

In the NPRM, the FAA proposed to require installing, on the right- and left-hand side divan, a protective fairing covering on the divan shroud and the sideledge panel, as specified in ANAC AD 2021–11–01R1.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–0873.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

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 referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

ANAC AD 2021–11–01R1 specifies procedures for installing, on the right- and left-hand side divan, a protective fairing covering on the divan shroud and the sideledge panel.

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.

Costs of Compliance

The FAA estimates that this AD affects 63 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 14 work-hours × $85 per hour = Up to $1,190	$400	Up to $1,590	Up to $100,170.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators. The FAA does not control warranty coverage for affected operators. As a result, the FAA has included all known costs in the cost estimate.

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:

2022–19–14 Embraer S.A.: Amendment 39–22183; FAA–2022–0873; Project Identifier MCAI–2022–00060–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 14, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model EMB–545 and EMB–550 airplanes, certificated in any category, as identified in paragraph (a)(2) of Agência Nacional de Aviação Civil (ANAC) AD 2021–11–01R1, effective January 21, 2022 (ANAC AD 2021–11–01R1).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report that there is a possibility of the shoulder belt

getting stuck during flight due to a step between the divan shroud chamfer and the sideledge panel. This set up may interfere with the correct kinematics of the shoulder belt during its retraction. The FAA is issuing this AD to address the possibility of a stuck shoulder belt during flight, which could affect the shoulder belt release during turbulence or an emergency landing situation and result in injury to passengers and the flightcrew.

(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, ANAC AD 2021–11–01R1.

(h) Exceptions to ANAC AD 2021–11–01R1

(1) Where ANAC AD 2021–11–01R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraph (b)(1) of ANAC AD 2021–11–01R1 do not apply to this AD.

(3) Where paragraph (b)(2) of ANAC AD 2021–11–01R1 specifies that it applies to certain airplanes, replace the text ''airplanes identified in paragraph (a)(2) of this [ANAC] AD, and which are not listed in the paragraph (a)(1) of this [ANAC] AD,'' with ''airplanes identified in paragraph (a)(2) of this [ANAC] AD.''

(4) The ''Alternative methods of compliance (AMOC)'' section of ANAC AD 2021–11–01R1 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* 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 responsible Flight Standards Office, as appropriate. If sending information directly to the Manager, International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(j) Related Information

For more information about this AD, contact Ho-Joon Lim, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3405; email *ho-joon.lim@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Agência Nacional de Aviação Civil (ANAC) AD 2021–11–01R1, effective January 21, 2022.

(ii) [Reserved]

(3) For ANAC AD 2021–11–01R1, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this ANAC AD on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 9, 2022.

Christina Underwood,

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

Editorial Note: This document was received for publication by the Office of the Federal Register on March 7, 2023.

[FR Doc. 2023–04936 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

INTERNATIONAL TRADE COMMISSION

19 CFR Parts 206 and 207

Implementing Rules for the United States-Mexico-Canada Agreement Implementation Act

AGENCY: United States International Trade Commission.

ACTION: Final rule.

SUMMARY: The United States International Trade Commission (Commission) is making technical amendments to its rules, relating to safeguard actions, and injury to domestic industries from imports sold at less than fair value or from subsidized exports, to conform with changes made by the United States-Mexico-Canada Agreement Implementation Act (USMCA Act).

DATES:

Effective date: April 10, 2023.

Applicability date: The date the Agreement Between the United States of America, the United Mexican States, and Canada entered into force, July 1, 2020.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary, United States International Trade Commission, telephone (202) 205–2000; William Gearhart, Office of the General Counsel, United States International Trade Commission, telephone (202) 205–3091; Garrett Peterson, Office of the General Counsel, United States International Trade Commission, telephone (202) 205–3241. Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website at *https://www.usitc.gov.*

SUPPLEMENTARY INFORMATION: The preamble below is designed to assist readers in understanding these technical amendments to the rules of practice and procedure to conform with the USMCA Act. This preamble provides background information, a regulatory analysis of the rules, a section-by-section explanation of amendments and new rules, and a description of the amendments and new rules.

These rules are being promulgated in accordance with the Administrative Procedure Act (5 U.S.C. 553) (APA), and will be codified in 19 CFR parts 206 and 207.

Background

On November 30, 2018, 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) was signed to replace the North American Free Trade Agreement (NAFTA). The Agreement Between the United States of America, the United Mexican States (Mexico), and Canada (the USMCA) 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,'' which the Office of the United States Trade Representative (USTR) signed on December 10, 2019.

The United States adopted the USMCA through the enactment of the USMCA Act on January 29, 2020, and the USMCA entered into force on July 1, 2020.

Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) (Tariff Act) authorizes the Commission to adopt such reasonable procedures, rules, and regulations as it deems necessary to carry out its functions and duties. In addition, sections 103(b) and 412(g) of the USMCA Act (19 U.S.C. 4513(b) and 4582(g), respectively) direct the Commission to prescribe implementing regulations necessary or appropriate to carry out actions required by or authorized by the USMCA Act.

The Commission is making technical amendments to existing rules of procedures and practice regarding the USMCA Act. In part 206, these include amendments that (1) implement provisions in section 301 of the Act that require the Commission to make special findings with respect to imports from Canada or Mexico if the Commission makes an affirmative determination in a global safeguard action investigation under section 202(b) of the Trade Act of 1974; and (2) delete references to U.S.-Canada and U.S.-Mexico bilateral safeguard actions, since section 601 of the USMCA Act repeals former statutory provisions that provided for such actions. In part 207, these include amendments to the provisions regarding the issuance of administrative protective orders (APOs) in binational dispute panels concerning antidumping and countervailing duty determinations now covered under section 422 of the USMCA Act.

A. Subparts B, C, and D of Part 206

Sections 301–302 of the USMCA Act implements the provisions of Article 10.2 of the USMCA concerning global safeguard investigations under section 202 of the Trade Act of 1974 (19 U.S.C. 2252). A similar provision appeared in sections 311–312 of the North American Free Trade Agreement Implementation Act (NAFTA Act); section 502(b)–(c) of the USMCA Act amended these provisions and transferred them to sections 301–302 of the USMCA Act. The USMCA Act retains without substantive change the global safeguard procedures established under the NAFTA Act. For example, these unaltered provisions required that, if the Commission finds that increased global imports are causing or threaten to cause serious injury to a domestic industry, the Commission also must provide factual findings to the President as to whether imports from Canada and/or Mexico ''account for a substantial share of imports'' and ''contribute importantly to the serious injury caused by U.S. imports'' (19 U.S.C. 4551(a)). The USMCA Act maintains these and all global safeguard provisions from the NAFTA Act while updating references to the applicable agreements and implementing laws, consistent with sections 301–302 of the USMCA Act.

Neither the USMCA Act nor the USMCA contains provisions for bilateral safeguard actions concerning imports from USMCA countries. Accordingly, section 601 of the USMCA Act repeals provisions under the NAFTA Act that had allowed for such investigations. Additionally, bilateral safeguard actions under the United States-Chile Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), the Dominican Republic Central American-United States Free Trade Agreement Implementation Act (19 U.S.C. 4064), and United States-Peru Trade Promotion Implementation Act (19 U.S.C. 3805 note) have expired.

B. Subpart G of Part 207

Section 422 of the USMCA Act amends U.S. law to implement Chapter 10, Section D of the USMCA, which retains the mechanism from NAFTA for the establishment of binational dispute panels to resolve disputes between any two of the USMCA countries with respect to antidumping and countervailing duty cases.

Section 422 strikes references to previous agreements and replaces them with references to either USMCA (for new binational disputes initiated after implementation of USMCA) or NAFTA (for prior binational disputes that are on-going following implementation of USMCA). Section 422 does not otherwise substantively alter previous procedures established under the NAFTA Act. Accordingly, these technical amendments largely maintain the rules of practice and procedure, adopted in 1995, concerning the protection of business proprietary information (BPI), and access to that information under APO, that had been implemented under the NAFTA Act, while updating references to the applicable agreements and implementing laws. These technical amendments also update certain provisions consistent with agency practice regarding electronic filing.

Procedure for Adopting the Amendments

The Commission ordinarily promulgates amendments to the Code of Federal Regulations in accordance with the notice-and-comment rulemaking procedure in section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). That procedure entails publication of proposed rulemaking in the **Federal Register** that solicits public comments on the amendments, consideration by the Commission of public comments on the contents of the amendments, and publication of the final amendments at least 30 days prior to their effective date.

In this instance, however, the Commission is amending rules in 19 CFR parts 206 and 207 on a final basis. The Commission's authority to adopt final amendments without following all steps listed in section 553 of the APA is derived from section 335 of the Tariff Act (19 U.S.C. 1335), sections 103(b) and 412(g) of the USMCA Act (19 U.S.C. 4513(b) and 4582, respectively), and section 553 of the APA.

Section 553(b) of the APA allows an agency to dispense with publication of a notice of proposed rulemaking when the agency for good cause finds that notice and public comment on the rules are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates that finding and the reasons therefor into the rules adopted by the agency. Section 553(d)(3) of the APA allows an agency to dispense with the publication of notice of final rules at least thirty days prior to their effective date if the agency finds that good cause exists for not meeting the advance publication requirements and the agency publishes that finding along with the rules.

In this instance, the Commission has determined that the requisite circumstances exist for dispensing with the notice, comment, and advance publication procedure that ordinarily precedes the adoption of Commission rules. The amendments to part 206 are technical amendments reflecting the retention in the USMCA Act of the precise requirements from the NAFTA Act for certain Commission findings concerning goods from Canada and/or Mexico when conducting a global safeguard investigation. The amendments to part 206 likewise reflect the expiration of provisions addressing bilateral safeguard actions involving USMCA countries. The amendments to part 207 are technical amendments, mostly involving changing references from the NAFTA Act to the USMCA Act, that do not alter the substance of agency procedures regarding the treatment of BPI in binational panel disputes. Given the technical nature of these amendments, the Commission has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment is unnecessary. Moreover, the Commission

finds under section 553(b)(3)(B) of the APA that good cause exists to waive prior notice and opportunity for comment. Under section 504(k)(1) of the USMCA Act (19 U.S.C. 4581), challenges to final antidumping and countervailing duty determinations initiated on or after July 1, 2020 will be subject to the provisions of the USMCA Act, and rules of procedure updating reference to the USMCA Act are thus necessary. Hence, it would be impracticable as well as unnecessary for the Commission to comply with the usual notice of proposed rulemaking and public comment procedure. Therefore, the Commission has determined to issue these technical amendments as final rules under these circumstances.

Regulatory Analysis of Amendments to the Commission's Rules

The Commission has determined that the technical amendments to the rules do not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993) and thus do not constitute a ''significant regulatory action'' for purposes of the Executive order.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of proposed rulemaking is required under 5 U.S.C. 553(b) or any other statute.

The final rules do not contain federalism implications warranting the preparation of a federalism summary impact statement pursuant to Executive Order 13132 (64 FR 43255, Aug. 4, 1999).

No actions are necessary under title II of the Unfunded Mandates Reform Act of 1995, Pubic Law 104–4 (2 U.S.C. 1531–1538), because the final rules will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation), and will not significantly or uniquely affect small governments, as defined in 5 U.S.C. 601(5).

These final rules are not ''major rules'' as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). Moreover, they are exempt from the reporting requirements of that Act because they contain rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

Section-by-Section Explanation of the Amendments

Part 206—Investigations Related to Global and Bilateral Safeguard Actions, Market Disruptions, Trade Diversion, and Review of Relief Actions

Section 206.1 is amended to remove references to the NAFTA Act and to add references to the USMCA Act.

Section 206.6 is amended to remove references to the NAFTA Act and to add references to the USMCA Act.

Section 206.14(i) is amended to remove references to NAFTA countries and to add references to USMCA countries.

The heading of subpart C of part 206 is amended to replace ''NAFTA'' with ''USMCA.''

Section 206.21 is amended to remove references to the NAFTA Act and to add references to the USMCA Act.

Section 206.23 is amended to remove references to the NAFTA Act and NAFTA countries and to add references to the USMCA Act and USMCA countries.

Section 206.24(c) is amended to remove a reference to NAFTA country and to add a reference to USMCA country.

Section 206.31 is amended to remove references to agreements whose bilateral safeguard provisions have expired, including the United States-Chile Free Trade Agreement Implementation Act, the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, the NAFTA Act, and the United States-Peru Trade Promotion Agreement Implementation Act.

Section 206.33(a) is amended to remove a reference to Canadian articles; § 206.33(b) is amended to remove references to free trade agreements whose bilateral safeguard provisions have expired; and § 206.33(c) and (d) are amended to remove references to Canada and Mexico.

Section 206.34's introductory text is amended to remove references to Canadian articles, Canada, and Mexico.

Section 206.37 is amended to remove a reference to NAFTA.

Part 207, Subpart G—Implementing Regulations for the United-States-Mexico-Canada Agreement Implementation Act

The heading of subpart G to part 207 is amended to replace ''North American Free Trade Agreement'' with ''United States-Mexico-Canada Agreement.''

Section 207.90 is amended to remove references to the NAFTA and NAFTA Act and to add references to the USMCA and USMCA Act.

Section 207.91 definitions are amended as follows: ''Agreement'' is amended to reference applicable agreements, including the USMCA and NAFTA; ''Article 1904 Rules'' is removed; ''Binational Panel Rules'' is added and defined as the Rules of Procedure for Article 10.12 published by the United States Trade Representative in 88 FR 10171, February 16, 2023, or, where applicable, Article 1904 of the NAFTA; ''Complaint'' is amended to reflect Binational Panel Rules; ''Counsel'' is amended to reflect the definition of counsel under applicable rules; ''Date of service'' is amended to add reference to electronic service; ''Days'' is amended to replace ''shall be'' with ''will be''; ''Extraordinary challenge committee'' is amended to add reference to the USMCA; ''ECC Rules'' is amended to add reference to the USMCA; ''Final determination'' is amended to add reference to the USMCA; ''Free Trade Area Country'' is amended to reference 19 U.S.C. 1516a(f)(9) instead of 19 U.S.C. 1516a(f)(10); ''NAFTA Act'' is removed; ''Notice of appearance'' is amended to reflect applicable rules; ''Panel review'' is amended to add reference to the USMCA; ''Relevant FTA Secretary'' is removed; ''Responsible Secretary'' is added and defined as the Secretary of the Section of the Secretariat located in the country in which the final determination under review was made; ''Secretariat'' is amended to include reference to the USMCA; ''Service address'' is amended to reflect Commission practice and to allow for electronic service; ''USMCA Act'' is added and defined as the United States-Mexico-Canada Implementation Act, Public Law 116–113 (January 29, 2020); reference to the definitions set forth in Article 1904 is amended to reference the definitions set forth in the Binational Panel Rules.

Section 207.92 is amended to remove references to the Department of Commerce regulations at 19 CFR part 356 and replace it with reference to ''Binational Panel Rules.''

Section 207.93(b)(6) and (c)(3) are amended to add reference to Secretaria de Economia; § 207.93(c)(2)(i) is amended to add reference to the website of the Commission Secretary; § 207.93(c)(2)(ii)(B) is amended to add reference to the USMCA; § 207.93(c)(4)(ii)(A) is amended to replace ''NAFTA'' with ''USMCA''; § 207.93(c)(4)(ii)(B) is amended to replace ''Article 1904 Panel ''with ''Binational Panel''; § 207.93(c)(4)(v) is amended to replace ''relevant FTA secretary'' with ''Responsible Secretary''; § 207.93(c)(5)(i) is amended

to replace ''NAFTA'' with ''USMCA''; § 207.93(c)(5)(ii)(A) and (B) are amended to replace ''NAFTA'' with ''USMCA''; and § 207.93(d)(1) is amended to replace ''United States-Canada Free Trade Agreement'' with ''NAFTA''.

Section 207.94 is amended to replace ''extraordinary challenge committee'' with the shorthand ''ECC.''

List of Subjects in 19 CFR Parts 206 and 207

Administrative practice and procedure, Trade agreements.

For the reasons stated in the preamble, the United States International Trade Commission amends 19 CFR parts 206 and 207 as follows:

PART 206—INVESTIGATIONS RELATING TO GLOBAL AND BILATERAL SAFEGUARD ACTIONS, MARKET DISRUPTION, TRADE DIVERSION, AND REVIEW OF RELIEF ACTIONS

■ 1. The authority citation for part 206 is revised to read as follows:

Authority: 19 U.S.C. 1335, 2112 note, 2251–2254, 2436, 3805 note, 4051–4065, 4101, and 4551–4552.

■ 2. Section 206.1 is revised to read as follows:

§ 206.1 Applicability of part.

This part applies to proceedings of the Commission under sections 201–202, 204, and 406 of the Trade Act of 1974, as amended (19 U.S.C. 2251–2252, 2254, and 2436), and sections 301–302 of the United States-Mexico-Canada Implementation Act (19 U.S.C. 4551–4552) (hereinafter USMCA Implementation Act), and the statutory provisions listed in § 206.31 that implement bilateral safeguard provisions in other free trade agreements into which the United States has entered.

Subpart A—General

■ 3. Section 206.6 is amended by revising paragraph (b)(2) to read as follows:

§ 206.6 Report to the President.

* * * * *

(b) * * *

(2) In the case of a determination made under section 301(b) of the USMCA Implementation Act, the Commission will include in its report the findings with respect to the results of an examination of the factors other than imports which may be a cause of serious injury or threat thereof to the domestic industry.

* * * * *

Subpart B—Investigations Relating to Global Safeguard Actions

■ 4. Section 206.14 is amended by revising paragraph (i) to read as follows:

§ 206.14 Contents of petition.

* * * * *

(i) *Imports from USMCA countries.* Quantitative data indicating the share of imports accounted for by imports from each USMCA country (Canada and Mexico), and petitioner's view on the extent to which imports from such USMCA country or countries are contributing importantly to the serious injury, or threat thereof, caused by total imports of such article.

* * * * *

■ 5. The heading for subpart C is revised to read as follows:

Subpart C—Investigations Relating to a Surge in Imports From a USMCA Country

■ 6. Section 206.21 is revised to read as follows:

§ 206.21 Applicability of subpart.

This subpart applies specifically to investigations under section 302 of the USMCA Implementation Act (19 U.S.C. 4552). For other applicable rules, see subpart A of this part and part 201 of this chapter.

■ 7. Section 206.23 is revised to read as follows:

§ 206.23 Who may file a request.

If the President, under section 302(b) of the USMCA Implementation Act (19 U.S.C. 4552(b)), has excluded imports from a USMCA country or countries from an action under chapter 1 of title II of the Trade Act of 1974, any entity that is representative of an industry for which such action is being taken may request the Commission to conduct an investigation to determine whether a surge in such imports undermines the effectiveness of the action.

■ 8. Section 206.24 is amended by revising paragraph (c) to read as follows:

§ 206.24 Contents of request.

* * * * *

(c) Data concerning imports from the USMCA country or countries that form the basis of requestor's claim that a surge in imports has occurred;

* * * * *

Subpart D—Investigations Relating to Bilateral Safeguard Actions

■ 9. Section 206.31 is revised to read as follows:

§ 206.31 Applicability of subpart.

This subpart applies specifically to investigations under section 311(b) of the United States-Australia Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Bahrain Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Colombia Trade Promotion Agreement Implementation Act (19 U.S.C. 3805 note), section 211(b) of the United States-Jordan Free Trade Area Implementation Act (19 U.S.C. 2112 note), section 311(b) of the United States-Korea Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Morocco Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Oman Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Panama Trade Promotion Agreement Implementation Act (19 U.S.C. 3805 note), and section 311(b) of the United States-Singapore Free Trade Agreement Implementation Act (19 U.S.C. 3805 note). For other applicable rules, see subpart A of this part and part 201 of this chapter.

■ 10. Section 206.33 is amended by revising paragraphs (a) through (d) to read as follows:

§ 206.33 Who may file a petition.

(a) *In general.* A petition under this subpart may be filed by an entity, including a trade association, firm, certified or recognized union, or group of workers, that is representative of a domestic industry producing an article that is like or directly competitive with an article that is allegedly, as a result of the reduction or elimination of a duty provided for under a free trade agreement listed in paragraph (b) of this section, being imported into the United States in such increased quantities, in absolute terms or relative to domestic production, and under such conditions that imports of the article constitute a substantial cause of serious injury, or threat thereof, to such domestic industry. Unless the implementation statute provides otherwise, a petition may be filed only during the transition period of the particular free trade agreement.

(b) *List of free trade agreements.* The free trade agreements referred to in paragraph (a) of this section include the

United States-Australia Free Trade Agreement, the United States-Bahrain Free Trade Agreement, the United States-Colombia Trade Promotion Agreement, the United States-Jordan Free Trade Area Agreement, the United States-Korea Free Trade Agreement, the United States-Morocco Free Trade Agreement, the United States-Oman Free Trade Agreement, the United States-Panama Trade Promotion Agreement, and the United States-Singapore Free Trade Agreement, to the extent that such agreements have entered into force.

(c) *Critical circumstances.* An entity of the type described in paragraph (a) of this section that represents a domestic industry may allege that critical circumstances exist and petition for provisional relief with respect to imports if such product is from Australia, Jordan, Korea, Morocco, or Singapore.

(d) *Perishable agricultural product.* An entity of the type described in paragraph (a) of this section that represents a domestic industry producing a perishable agricultural product may petition for provisional relief with respect to imports of such product from Australia, Jordan, Korea, Morocco, or Singapore, but only if such product has been subject to monitoring by the Commission for not less than 90 days as of the date the allegation of injury is included in the petition.

* * * * *

■ 11. Section 206.34 is amended by revising the introductory text to read as follows:

§ 206.34 Contents of petition.

A petition under this subpart shall include specific information in support of the claim that, as a result of the reduction or elimination of a duty provided for under a free trade agreement listed in § 206.33(b), an article is being imported into the United States in such increased quantities, in absolute terms or relative to domestic production, and under such conditions that imports of the article constitute a substantial cause of serious injury, or threat thereof, to the domestic industry producing an article that is like or directly competitive with the imported article. If provisional relief is requested in a petition concerning an article from Australia, Jordan, Korea, Morocco, or Singapore, the petition shall state whether provisional relief is sought because critical circumstances exist or because the imported article is a perishable agricultural product. In addition, a petition filed under this subpart shall include the following information, to the extent that such information is publicly available from governmental or other sources, or best estimates and the basis therefor if such information is not available:

* * * * *

■ 12. Section 206.37 is revised to read as follows:

§ 206.37 Limited disclosure of certain confidential business information under administrative protective order.

Except in the case of an investigation under the United States-Jordan Free Trade Area Implementation Act, the Secretary shall make available to authorized applicants, in accordance with the provisions of § 206.17, confidential business information obtained in an investigation under this subpart.

PART 207—INVESTIGATIONS OF WHETHER INJURY TO DOMESTIC INDUSTRIES RESULTS FROM IMPORTS SOLD AT LESS THAN FAIR VALUE OR FROM SUBSIDIZED EXPORTS TO THE UNITED STATES

■ 13. The authority citation for part 207 is revised to read as follows:

Authority: 19 U.S.C. 1335, 1671–1677n, 2482, 3513, 4582.

■ 14. The heading for subpart G is revised and the authority citation for subpart G is removed.

The revision reads as follows:

Subpart G—Implementing Regulations for the United States-Mexico-Canada Agreement

■ 15. Section 207.90 is revised to read as follows:

§ 207.90 Scope.

This subpart sets forth the procedures and regulations for implementation of Section D of Chapter 10 of the Agreement between the United States of America, the United Mexican States, and Canada, as provided by Section 422(a) of the United States-Mexico-Canada Implementation Act (19 U.S.C. 1677(f)). These regulations are authorized by section 412(g), as amended by section 504(c)(3)(G), of the United States-Mexico-Canada Implementation Act and 19 U.S.C. 4582.

■ 16. Section 207.91 is revised and republished to read as follows:

§ 207.91 Definitions.

Except as otherwise provided in this subpart, the definitions set forth in the Binational Panel Rules and the ECC Rules (as defined in this section) are applicable to this subpart and to any protective orders issued pursuant to this subpart. As used in this subpart—

Administrative Law Judge means the United States Government employee appointed under 5 U.S.C. 310(f) to conduct proceedings under this part in accordance with 5 U.S.C. 554.

Agreement means Article 10.12 of the Agreement between the United States of America, the United Mexican States (''Mexico''), and Canada entered into among these states, effective July 1, 2020 (''USMCA''); or, with respect to binational panel proceedings between either of Canada and the United States or Mexico and the United States underway as of the date of enactment of the Agreement, it means the Article 1904 of the North American Free Trade Agreement entered into between the governments of the United States of America, Mexico, and Canada, effective January 1, 1994 (''NAFTA'').

Binational Panel Rules means the Rules of Procedure for Article 10.12 published by the United States Trade Representative in 88 FR 10171, February 16, 2023, or, where applicable, Article 1904 of the NAFTA.

Canadian Secretary means the Secretary of the Canadian section of the Secretariat and includes any person authorized to act on the Secretary's behalf.

Charged party means a person who is charged by the Commission with committing a prohibited act under 19 U.S.C. 1677f(f)(3).

Clerical person means a person such as a paralegal, secretary, or law clerk who is employed or retained by and under the direction and control of an authorized applicant.

Commission means the United States International Trade Commission.

Commission Secretary means the Secretary to the Commission.

Complaint means the complaint referred to in the Binational Panel Rules.

Counsel means a person entitled to appear as counsel before a Federal court in the United States, consistent with the Binational Panel and ECC Rules, and counsel for an interested person who plans to file a timely complaint or notice of appearance in the panel review.

Date of service means the day a document is deposited in the mail, electronically sent, or delivered in person, as applicable.

Days means calendar days, but if a deadline falls on a weekend or United States Federal holiday, it will be extended to the next working day.

ECC Rules means the Rules of Procedure for Annex 10–B.3 published by the United States Trade

Representative in 88 FR 10171, February 16, 2023, or, where applicable, Annex 1904.13 of the NAFTA.

Extraordinary challenge committee (''ECC'') means the committee established to review decisions of a panel or conduct of a panelist, pursuant to Annex 10–B.3 to Chapter 10 of the USMCA or to Annex 1904.13 of the NAFTA.

Final determination means ''final determination'' under Article 10.8 of the USMCA or Article 1911 of the NAFTA.

Free Trade Area country means the ''free trade area country'' as defined in 19 U.S.C. 1516a(f)(9).

Investigative attorney means an attorney designated by the Office of Unfair Import Investigations to engage in inquiries and proceedings under §§ 207.100 through 207.120.

Mexican Secretary means the Secretary of the Mexican section of the Secretariat and includes any persons authorized to act on the Secretary's behalf.

Notice of appearance means the notice of appearance provided for by the Binational Panel Rules or ECC Rules, as applicable.

Panel review means review of a final determination, including review by an extraordinary challenge committee, pursuant to Section D of Chapter 10 of the USMCA or Chapter 19 of the NAFTA.

Party means, for the purposes of §§ 207.100 through 207.120, either the investigative attorney(ies) or the charged party(ies).

Person means, for the purposes of §§ 207.100 through 207.120, an individual, partnership, corporation, association, organization, or other entity.

Privileged information means all information covered by the provisions of the second sentence of 19 U.S.C. 1677f(f)(1)(A).

Professional means an accountant, economist, engineer, or other non-legal specialist who is employed by, or under the direction and control, of a counsel.

Prohibited act means the violation of a protective order, the inducement of a violation of a protective order, or the knowing receipt of information the receipt of which constitutes a violation of a protective order.

Proprietary information means confidential business information as defined in 19 CFR 201.6(a).

Protective order means an administrative protective order issued by the Commission.

Responsible Secretary means the Secretary of the Section of the Secretariat located in the country in which the final determination under review was made.

Secretariat means the Secretariat established pursuant to Article 30.6 of the USMCA and Article 2002 of the NAFTA, and includes the Secretariat sections located in Canada, the United States, and Mexico.

Service address means the address filed with the Secretariat as the service address for that person, including any electronic mail address submitted with that address.

Service list means the list maintained by the Commission Secretary under 19 CFR 201.11(d) of persons in the administrative proceeding leading to the final determination under panel review.

United States Secretary means the Secretary of the United States section of the Secretariat and includes any person authorized to act on the Secretary's behalf.

USMCA Act means the United States-Mexico-Canada Implementation Act, Public Law 116–113 (January 29, 2020).

■ 17. Section 207.92 is revised to read as follows:

§ 207.92 Procedures for commencing review of final determinations.

(a) *Notice of Intent to Commence Judicial Review.* A Notice of Intent to Commence Judicial Review shall contain such information, and be in such form, manner, and style, including service requirements, as prescribed by the Binational Panel Rules.

(b) *Request for Panel Review.* A Request for Panel Review shall contain such information, and be in such form, manner, and style, including service requirements, as prescribed by the Binational Panel Rules.

■ 18. Section 207.93 is amended by revising paragraphs (b) introductory text, (b)(6), (c)(2)(i), (c)(2)(ii)(B), (c)(3), (c)(4)(ii)(A) and (B), (c)(4)(v), (c)(5)(i) and (ii), and (d)(1) to read as follows:

§ 207.93 Protection of proprietary information during panel and committee proceedings.

* * * * *

(b) *Persons authorized to receive proprietary information under protective order.* The following persons may be authorized by the Commission to receive access to proprietary information if they comply with the regulations in this section and such other conditions imposed upon them by the Commission:

* * * * *

(6) Any officer or employee of the Government of Canada or the Government of Mexico who the Canadian Minister of Trade or the Mexican Secretary of Economia (*Secretaría de Economía*), as the case may be, informs the Commission Secretary needs access to proprietary information to make recommendations regarding the convening of extraordinary challenge committees; and

* * * * *

(c) * * *

(2) * * *

(i) The Commission Secretary shall adopt from time to time forms for submitting requests for release pursuant to protective order that incorporate the terms of this section. The Commission Secretary shall supply the United States Secretary with copies of the forms for persons described in paragraphs (b)(1), (4), (5), and (6) of this section. Other applicants may obtain the forms at the Commission Secretary's office at 500 E Street SW, Washington, DC 20436, or from the website of the Commission Secretary.

(ii) * * *

(B) Not use any of the proprietary information released under protective order and not otherwise available for purposes other than the particular proceedings under Section D of Chapter 10 of the USMCA, or Article 1904 of the NAFTA, as applicable;

* * * * *

(3) *Timing of applications.* An application for any person described in paragraph (b)(1) or (2) of this section may be filed after a notice of request for panel review has been filed with the Secretariat. A person described in paragraph (b)(4) of this section shall file an application immediately upon assuming official responsibilities in the United States, Canadian, or Mexican Secretariat. An application for any person described in paragraph (b)(5) or (6) of this section may be filed at any time after the United States Trade Representative, the Canadian Minister of Trade, or the Mexican Secretaría de Economía, as the case may be, has notified the Commission Secretary that such person requires access.

* * * * *

(4) * * *

(ii) * * *

(A) *Filing.* A person described in paragraph (b)(2) of this section, concurrent with the filing of a complaint or notice of appearance in the panel review on behalf of the participant represented by such person, shall file the completed original of the form (USMCA APO Form C) and three (3) copies with the Commission Secretary, and four (4) copies with the United States Secretary.

(B) *Service.* If an applicant files before the deadline for filing notices of

appearance for the panel review, the applicant shall concurrently serve each person on the service list with a copy of the application. If the applicant files after the deadline for filing notices of appearance for the panel review, the applicant shall serve each participant in the panel review in accordance with the applicable Binational Panel Rules and ECC Rules. Service on a person may be effected by delivering a copy to the person's service address; by sending a copy to the person's service address by facsimile transmission, expedited courier service, expedited mail service; or by personal service.

* * * * *

(v) *Applications of persons described in paragraph (b)(6) of this section.* A person described in paragraph (b)(6) of this section shall submit the completed original of the protective order application to the Responsible Secretary. The Responsible Secretary in turn, shall file the original and three (3) copies with the Commission Secretary.

(5) * * *

(i) If counsel or a professional has been granted access in an administrative proceeding to proprietary information under a protective order that contains a provision governing continued access to that information during panel review, and that counsel or professional retains the proprietary information more than fifteen (15) days after a First Request for Panel Review is filed with the Secretariat, that counsel or professional, and such clerical persons with access on or after that date, become immediately subject to the terms and conditions of USMCA APO Form C maintained by the Commission Secretary on that date including provisions regarding sanctions for violations thereof.

(ii) Any person described in paragraph (c)(5)(i) of this section, concurrent with the filing of a complaint or notice of appearance in the panel review on behalf of the participant represented by such person, shall:

(A) File the completed original of the form (USMCA APO Form C) and three (3) copies with the Commission Secretary; and

(B) File four (4) copies of the completed USMCA APO Form C with the United States Secretary.

* * * * *

(d) * * *

(1) *Applicants described in paragraphs (b)(1), (4), (5), and (6) of this section.* Upon approval of an application of persons described in paragraph (b)(1), (4), (5), or (6) of this section, the Commission Secretary shall issue a protective order permitting release of proprietary information. Any member of a binational panel proceeding initiated under the NAFTA to whom the Commission Secretary issues a protective order must countersign it and return one copy of the countersigned order to the United States Secretary. Any other applicant under paragraph (b)(1) of this section must file a copy of the order with the United States Secretary.

* * * * *

■ 19. Section 207.94 is revised to read as follows:

§ 207.94 Protection of privileged information during panel and committee proceedings.

If a panel or ECC decides that the Commission is required, pursuant to the United States law, to grant access pursuant to a protective order to information for which the Commission has claimed a privilege, any individual to whom the panel or ECC has directed the Commission release information and who is otherwise within the category of individuals eligible to receive proprietary information pursuant to § 207.93(b), may file an application for a protective order with the Commission. Upon receipt of such application, the Commission Secretary shall certify to the Commission that a panel or ECC has required the Commission to release such information to specified persons, pursuant to 19 U.S.C. 1677f(f)(1). Twenty-four hours following such certification, the Commission Secretary shall issue a protective order releasing such information to any authorized applicant subject to terms and conditions equivalent to those described in § 207.93(c)(2).

By order of the Commission.

Issued: February 16, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–03662 Filed 3–9–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, 528, and 558

[Docket No. FDA–2022–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective March 10, 2023.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM

FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2022 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
July 18, 2022	141–043	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SYNOVEX Choice and SYNOVEX Plus (trenbolone acetate and estradiol benzoate implants) Implants.	Supplemental approval of a reimplantation program for growing beef steers and heifers fed in confinement for slaughter for increased rate of weight gain for up to 200 days.	FOI Summary, EA, FONSI.	522.2478
July 18, 2022	141–348	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SYNOVEX ONE Feedlot (trenbolone acetate and estradiol benzoate extended-release implants) Implants.	Supplemental approval of a reimplantation program for growing beef steers and heifers fed in confinement for slaughter for increased rate of weight gain for up to 200 days.	FOI Summary, EA, FONSI.	522.2478
July 19, 2022	200–724	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Lubabegron, monensin, and tylosin Type C medicated feeds.	Original approval for use of EXPERIOR (lubabegron Type A medicated article) with MONOVET (monensin Type A medicated article) and TYLOVET (tylosin phosphate Type A medicated article) in the manufacture of Type C medicated cattle feeds as a generic copy of NADA 141–512.	FOI Summary	558.625
July 19, 2022	200–725	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Lubabegron and monensin Type C medicated feeds.	Original approval for use of EXPERIOR (lubabegron Type A medicated article) with MONOVET (monensin Type A medicated article) in the manufacture of Type C medicated cattle feeds as a generic copy of NADA 141–514.	FOI Summary	558.330
July 28, 2022	141–564	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	Chlortetracycline and monensin Type C medicated feeds.	Original approval for use of PENNCHLOR (chlortetracycline Type A medicated article) and RUMENSIN (monensin Type A medicated article) in the manufacture of Type C medicated cattle feeds.	FOI Summary	558.128
July 29, 2022	200–726	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	Firocoxib Tablets for Horses (firocoxib tablets).	Original approval for the control of pain and inflammation associated with osteoarthritis in horses as a generic copy of NADA 141–458.	FOI Summary	520.928
July 29, 2022	200–727	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin, 1, Ireland.	Meloxicam 5 mg/mL Solution for Injection.	Original approval for the control of pain and inflammation in dogs and cats as a generic copy of NADA 141–219.	FOI Summary	522.1367
August 9, 2022	141–459	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO (fluralaner topical solution) for Cats.	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 12 weeks in cats and kittens.	FOI Summary	524.998
August 9, 2022	141–518	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO PLUS (fluralaner and moxidectin topical solution) for Cats.	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 2 months in cats and kittens.	FOI Summary	524.1001
August 11, 2022	141–565	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	Bacitracin and monensin Type C medicated feeds.	Original approval of PENNITRACIN MD (bacitracin Type A medicated article) and COBAN (monensin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of mortality caused by necrotic enteritis, or for increased rate of weight gain and improved feed efficiency, and as an aid in the prevention of coccidiosis in broiler chickens, laying hen replacement chickens, and layer breeder replacement chickens.	FOI Summary	558.355
September 6, 2022	141–462	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W Burr Blvd., Suite 21, Teaneck, NJ 07666.	Virginiamycin and narasin Type C medicated feeds.	Original approval of STAFAC (virginiamycin Type A medicated article) and MONTEBAN (narasin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary	558.635

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2022 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
September 6, 2022	141–429	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W Burr Blvd., Suite 21, Teaneck, NJ 07666.	Virginiamycin, narasin, and nicarbazin Type C medicated feeds.	Original approval of STAFAC (virginiamycin Type A medicated article) and MAXIBAN (narasin and nicarbazin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary	558.635
September 9, 2022	141–553	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007.	VALCOR (doramectin and levamisole injection) Injectable Solution.	Original approval for the treatment and control of certain gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites in cattle; and for revising the tolerance for residues of doramectin in the target tissue, cattle liver.	FOI Summary	522.772
September 28, 2022	200–719	Vetoquinol USA, Inc., 4250 N Sylvania Ave., Fort Worth, TX 76137.	SIMPLERA (florfenicol, terbinafine, mometasone furoate) Otic Solution.	Original approval for the treatment of otitis externa in dogs as a generic copy of NADA 141–440.	FOI Summary	524.957
September 29, 2022	200–694	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	SPECTOGARD (spectinomycin sulfate) Injectable Solution.	Original approval for the treatment of bovine respiratory disease as a generic copy of NADA 141–077.	FOI Summary	522.2121

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over-the-counter (OTC) to by veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 11, 2021 (*https://www.fda.gov/media/130610/download*).

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2022, TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO RX

Approval date	File No.	Sponsor	Product name	21 CFR section
July 7, 2022	041–629	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SPECTOGARD (spectinomycin) Solution	520.2123c.
July 7, 2022	055–072	Do	ALBACILLIN (penicillin G procaine and novobiocin sodium) Intramammary Infusion.	526.1698.
July 19, 2022	041–245	Do	ALBON (sulfadimethoxine) Injection 40%	522.2220.
July 29, 2022	055–098	Do	ALBADRY PLUS (penicillin G procaine and novobiocin sodium) Intramammary Infusion.	526.1698.
July 29, 2022	012–965	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	TYLAN 50 (tylosin) Injection and TYLAN 200 (tylosin) Injection	522.2640.
July 29, 2022	011–060	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	TERRAMYCIN (oxytetracycline HCl) Tablets	520.1660c.
July 29, 2022	140–909	Do	SULKA–S (sulfamethazine) Bolus	520.2260a.
July 29, 2022	094–114	Do	TERRAMYCIN 100 (oxytetracycline HCl) Injectable Solution; and LIQUAMYCIN 100 (oxytetracycline HCl) Injectable Solution.	522.1662a.
August 3, 2022	037–586	Do	ERYTHROMAST 36 (erythromycin) Intramammary Infusion	526.820.
August 5, 2022	065–124	Do	Tetracycline Intramuscular Vet (tetracycline) Injection	Not codified.
August 11, 2022	031–944	Do	DYNAMXYIN (sulfomyxin) Injectable	522.2340.
August 16, 2022	065–130	Do	CRYSTALLINE PRO PENICILLIN G (penicillin G procaine) Injectable Suspension.	522.1696b.
August 30, 2022	099–402	Do	OXYVET and AQUACHEL (oxytetracycline hydrochloride) Injectable Solution.	522.1662a.
September 22, 2022	008–763	Do	TERRAMYCIN (oxytetracycline hydrochloride and polymyxin B sulfate) Ophthalmic Ointment.	524.1662b.
September 23, 2022	091–127	Do	OXYVET Injection (oxytetracycline hydrochloride) Injectable Solution.	522.1662a.
September 23, 2022	048–287	Huvepharma EEOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Oxytetracycline 50 (oxytetracycline hydrochloride) Injectable Solution.	522.1662a.

II. Changes of Sponsorship

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, the applications to another sponsor, as listed in table 3.

TABLE 3—CHANGES OF SPONSORSHIP DURING JULY, AUGUST, AND SEPTEMBER 2022

File No.	Product name	Transferring sponsor	New sponsor	21 CFR section
039–583	GRANULEX V (balsam Peru oil, castor oil, trypsin).	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	524.2620.
141–513	ZIMETA (dipyrone) Injectable Solution.	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010.	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.	522.728.

Following these changes of sponsorship, Kindred Biosciences, Inc. is no longer the sponsor of an approved application. Accordingly, the drug labeler code for this firm will be removed from § 510.600(c) (21 CFR 510.600(c)).

III. Withdrawals of Approval

LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702 has requested that FDA withdraw approval of NADA 141–294 for a Bc6 rDNA construct in GTC 155–92 Goats because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 528.1070 are amended to reflect this action and in § 510.600(c) to reflect that LFB USA, Inc. is no longer the sponsor of an approved application.

IV. Change of Sponsor Name and Address

Akorn Animal Health, Inc., 1925 West Field Ct., Suite 300, Lake Forest, IL 60045 has informed FDA that it has changed its name and address to Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031. As provided in the regulatory text, § 510.600(c) is amended to reflect this change.

V. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 510.600(c) is amended to revise the names and addresses of Akorn Animal Health, Inc.; Mylan Institutional, Inc.; and Mylan Institutional LLC in the list of sponsors of approved applications and to remove Kindred Biosciences, Inc.
- 21 CFR 520.154a is amended to add instructions for administration of bacitracin methylenedisalicylate soluble powder in drinking water of chickens, turkeys, and swine.
- 21 CFR 522.840 is amended to reflect revised conditions of use for estradiol sustained-release implants in beef steers and heifers.
- 21 CFR 522.1372 is amended to reflect the correct volume of mepivacaine solution for nerve blocks used in horses.
- 21 CFR 522.1702 is redesignated to list it in a correct alphabetical sequence.
- 21 CFR 558.128 is amended to reflect the correct terminology for chlortetracycline Type C free-choice cattle feeds used for control of anaplasmosis.
- 21 CFR 558.258 is amended to reflect approved conditions of use for free-choice fenbendazole protein and mineral blocks in beef cattle.
- 21 CFR 558.330 is amended to add a previously uncodified concentration of lubabegron Type A medicated article for use in the manufacture of Type C feeds for beef steers and heifers fed in confinement for slaughter.
- 21 CFR 558.366 is amended to correctly describe the target class for nicarbazin medicated chicken feeds.
- 21 CFR 558.450 is amended to revise the instructions for use of oxytetracycline medicated feeds in breeding swine.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 528

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 526, 528, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), revise the entry for ''Akorn Animal Health, Inc.'', remove the entries for ''Kindred Biosciences, Inc.'' and ''LFB USA, Inc.'', and revise the entries for ''Mylan Institutional, Inc.'' and ''Mylan Institutional LLC''; and

■ b. In the table in paragraph (c)(2), revise the entries for ''051079'', ''059399'', and ''063286'' and remove the entries for ''086047'' and ''086078''.

The revisions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031	059399
* * * * * * *	
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505	063286
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.
* * * * * * *	
059399	Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.
* * * * * * *	
063286	Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. In § 520.154a:

■ a. Redesignate paragraphs (d)(1) and (2) as paragraphs (d)(2) and (1), respectively;

■ b. In newly redesignated paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), and (d)(2)(iii), add a sentence to the end of the paragraph; and

■ c. Revise paragraph (d)(3)(iii).

The additions and revision read as follows:

§ 520.154a Bacitracin methylenedisalicylate.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) * * * Use as the sole source of drinking water.

(ii) * * *

(B) * * * Use as the sole source of drinking water.

(2) * * *

(iii) * * * Use as the sole source of drinking water.

(3) * * *

(iii) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water. Treatment not to exceed 14 days. Not to be given to swine that weigh more than 250 pounds.

* * * * *

§ 520.928 [Amended]

■ 5. In § 520.928, in paragraph (b)(2), remove ''No. 000010'' and in its place add ''Nos. 000010 and 055246''.

■ 6. In § 520.1660c, revise the section heading and paragraph (d)(3) to read as follows:

§ 520.1660c Oxytetracycline hydrochloride tablets and boluses.

* * * * *

(d) * * *

(3) *Limitations*—(i) For No. 000010: Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily).

(ii) For No. 054771: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 7. In § 520.2123c, revise paragraph (d)(3) to read as follows:

§ 520.2123c Spectinomycin solution.

* * * * *

(d) * * *

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 8. In § 520.2260a, revise paragraph (d)(2)(iii) to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.728 [Amended]

■ 10. In 522.728, in paragraph (b), remove ''086078'' and in its place add ''043264''.

■ 11. Add § 522.772 to read as follows:

§ 522.772 Doramectin and levamisole.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) of doramectin and 150 mg levamisole hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.222 and 556.350 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Inject subcutaneously in the neck as a single dose at a dosage of 0.2 mg doramectin (0.91 mg/lb) and 6 mg of levamisole hydrochloride per kg (2.72 mg/lb) of body weight.

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, T. longispicularis, Cooperia oncophora, C. pectinata, C. punctata, C. surnabada, Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum, Trichuris spp.* (adults only) and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus;* eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum;* sucking lice: *Haematopinus eurysternus, Linognathus vituli,* and *Solenopotes capillatus;* mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 15 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

(2) [Reserved]

■ 12. In § 522.840, revise paragraphs (d)(1) and (2) and remove paragraph (d)(3).

The revisions read as follows:

§ 522.840 Estradiol.

* * * * *

(d) * * *

(1) *Amounts and indications for use*—(i) *25.7-mg extended-release implant.* Insert one implant for increased rate of weight gain for up to 200 days in beef steer calves 2 months of age and older; for increased rate of weight gain for up to 200 days in growing beef steers and heifers on pasture (stocker, feeder, and slaughter); and for increased rate of weight gain and improved feed efficiency for up to 200 days in growing beef steers and heifers fed in confinement for slaughter.

(ii) *43.9-mg extended-release implant.* Insert one implant for increased rate of weight gain for up to 400 days in beef steer calves 2 months of age and older; for increased rate of weight gain for up to 400 days in growing beef steers and heifers on pasture (stocker, feeder, and slaughter); and for increased rate of weight gain and improved feed efficiency for up to 400 days in growing beef steers and heifers fed in confinement for slaughter.

(2) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within each separate production phase (beef steer calves 2 months of age and older, growing beef steers on pasture (stocker, feeder, and slaughter), growing beef steers and heifers fed in confinement for slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

■ 13. In § 522.1367, revise paragraph (b) to read as follows:

§ 522.1367 Meloxicam.

* * * * *

(b) *Sponsors.* See Nos. 000010, 016729, 017033, 055529, and 086101 in § 510.600(c) of this chapter.

* * * * *

§ 522.1372 [Amended]

■ 14. In § 522.1372, in paragraph (c)(1), remove ''3 to 5 mL'' and in its place add ''3 to 15 mL''.

§§ 522.1662a and 522.1662b [Redesignated as § 522.1662 and § 522.1663]

■ 15. Redesignate §§ 522.1662a and 522.1662b as §§ 522.1662 and 522.1663, respectively.

■ 16. In newly redesignated § 522.1662:

■ a. Revise the section heading;

■ b. Add headings to paragraphs (b)(3)(i) through (iii);

■ c. Remove paragraph (b)(3)(iv); and

■ d. Revise paragraphs (d), (e), (f), and (i)(1) through (3).

The revisions and additions read as follows:

§ 522.1662 Oxytetracycline.

* * * * *

(b) * * *

(3) * * *

(i) *Amount.* * * *

(ii) *Indications for use.* * * *

(iii) *Limitations.* * * *

* * * * *

(d)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 15 days

prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains 50 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle.* It is used as follows:

(i) *Amount.* Administer by intravenous or intramuscular injection at 3 to 5 mg/lb of body weight per day, not exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Haemophilus spp.;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresii;* leptospirosis caused by *Leptospira pomona;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms; and treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Conditions of use in swine.* It is used in swine as follows:

(i) *Amount.* Administer by intramuscular injection at 3 to 5 mg/lb of body weight per day to swine, not to exceed a total of 4 consecutive days. Administered to sows at 3 mg/lb of body weight approximately 8 hours before farrowing or immediately after farrowing.

(ii) *Indications for use.* It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.* Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(iii) *Limitations.* Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Poultry (broilers, turkeys, and breeding chickens).* It is used as follows:

(i) *Amount.* Administer subcutaneously to chickens and turkeys according to age as directed on labeling.

(ii) *Indications for use.* For the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli;* fowl cholera caused by *Pasteurella multocida;* infectious sinusitis caused by *Mycoplasma gallisepticum;* and infectious synovitis caused by *Mycoplasma synoviae.*

(iii) *Limitations.* Do not administer to laying hens unless the eggs are used for hatching only. Discontinue treatment at least 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 15 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

(i) * * *

(1) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(i) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella spp.;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresii;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 18 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 17. In § 522.1696b, revise paragraphs (b)(2), (d)(1)(i), and (d)(2)(iii)(B) and add paragraph (d)(2)(iii)(C) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(b) * * *

(2) Nos. 055529 and 061133 for use as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 10,000 units per pound body weight daily by intramuscular injection.

* * * * *

(2) * * *

(iii) * * *

(B) For Nos. 016592 and 055529: Treatment should not exceed 4 consecutive days. A withdrawal period has not been established for this product in pre-ruminating calves. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7.

(C) For No. 054771: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1702 [Redesignated as § 522.1698]

■ 18. Redesignate § 522.1702 as § 522.1698.

§ 522.2121 [Amended]

■ 19. In § 522.2121, in paragraph (b), remove ''No. 054771'' and in its place add ''Nos. 054771 and 061133''.

■ 20. In § 522.2220, revise paragraph (d)(4)(iii) to read as follows:

§ 522.2220 Sulfadimethoxine.

* * * * *

(d) * * *

(4) * * *

(iii) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 21. In § 522.2340, revise paragraph (e)(4) to read as follows:

§ 522.2340 Sulfomyxin.

* * * * *

(e) * * *

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter. Do not treat turkeys within 7 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 22. Revise § 522.2478 to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications.* (1) Each implant consists of:

(i) 100 milligrams (mg) trenbolone acetate and 14 mg estradiol benzoate (one implant consisting of four pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(2) Each extended-release implant consists of:

(i) 150 mg trenbolone acetate and 21 mg estradiol benzoate (one implant consisting of six pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Growing beef steers and heifers fed in confinement for slaughter*—(i) *Amounts and indications for use*—(A) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain in growing beef steers fed in confinement for slaughter and for increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(i) or (ii) or (a)(2)(ii) of this section is administered 60 to 120 days later.

(B) An implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter and for increased rate of weight gain in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered 60 to 120 days later.

(C) An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(D) An extended-release implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency for up to 200 days. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(2)(ii) of this section is administered 60 to 120 days later.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than as described on the labeling, this implant is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. The extended-release implant described in paragraph (a)(2)(i) of this section, used as described in paragraph (d)(1)(i)(C) of this section, is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant.

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amounts and indications for use.* An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

■ 23. In § 522.2640, revise paragraphs (b)(1), (e)(1)(iii), and (e)(2)(iii) to read as follows:

§ 522.2640 Tylosin.

* * * * *

(b) * * *

(1) No. 058198 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. For No. 058198: Federal law

restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product. For No. 058198: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 24. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.957 [Amended]

■ 25. In § 524.957, in paragraph (b), remove ''No. 058198'' and in its place add ''Nos. 017030 and 058198''.

■ 26. In § 524.998, revise paragraph (c)(2)(ii) to read as follows:

§ 524.998 Fluralaner.

* * * * *

(c) * * *

(2) * * *

(ii) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*) and the treatment and control of *I. scapularis* (black-legged tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater; for the treatment and control of *D. variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater.

* * * * *

■ 27. In § 524.1001, revise paragraph (c)(2) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati,* fourth-stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme,* fourth-stage larvae, immature adults, and adults); kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

* * * * *

■ 28. In § 524.1662b, revise paragraph (c)(3) to read as follows:

§ 524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.

* * * * *

(c) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.2620 [Amended]

■ 29. In § 524.2620, in paragraph (b)(1), remove ''051079'' and in its place add ''069043''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 30. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 31. In § 526.820, revise paragraphs (d)(3) and (e)(3) to read as follows:

§ 526.820 Erythromycin.

* * * * *

(d) * * *

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) * * *

(3) *Limitations.* For use in dry cows only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 32. In § 526.1698, revise paragraphs (d)(3) and (e)(3) to read as follows:

§ 526.1698 Penicillin G procaine and novobiocin.

* * * * *

(d) * * *

(3) *Limitations.* For udder instillation in lactating cows only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) * * *

(3) *Limitations.* For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 528—INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

■ 33. The authority citation for part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 528.1070 [Removed]

■ 34. Remove § 528.1070.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 35. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 36. In § 558.128:

■ a. Redesignate paragraphs (e)(4)(x) through (xlvii) as paragraphs (e)(4)(xxi) through (lviii);

■ b. Redesignate paragraphs (e)(4)(vii) through (ix) as paragraphs (e)(4)(xv) through (xvii);

■ c. Redesignate paragraphs (e)(4)(iii) through (vi) as paragraphs (e)(4)(v) through (viii);

■ d. Revise newly redesignated paragraph (e)(4)(xv); and

■ e. Add new paragraphs (e)(4)(iii) and (iv), (ix) through (xiv), and (xviii) through (xx).

The revision and additions read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * * *	
(iii) 7 to 17.5 g/ton	Monensin, 5 to 40.	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for improved feed efficiency.	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(iv) 7 to 17.5 g/ton	Monensin, 10 to 40.	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
*	*	*	* * * *	
(ix) 33.33 to 66.67 g/ton	Monensin, 5 to 40.	Growing beef steers and heifers fed in confinement for slaughter over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(x) 33.33 to 66.67 g/ton	Monensin, 10 to 40.	Growing beef steers and heifers fed in confinement for slaughter over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xi) 50 to 117 g/ton	Monensin, 7.14 to 40.	Growing beef steers and heifers fed in confinement for slaughter under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xii) 50 to 117 g/ton	Monensin, 10 to 40.	Growing beef steers and heifers fed in confinement for slaughter under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xiii) 50 to 117 g/ton	Monensin, 7.14 to 40.	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xiv) 50 to 117 g/ton	Monensin, 10 to 40.	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xv) to provide 0.5 to 2.0 mg/lb of body weight daily.	.....	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	In Type C free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * * *	
(xviii) 400 to 2,000 g/ton.	Monensin, 5 to 40.	Growing beef steers and heifers fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for improved feed efficiency.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day. Treat for not more than 5 days, then continue feeding monensin Type C medicated feed alone. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xix) 400 to 2,000 g/ton	Monensin, 5 to 40.	Growing beef steers and heifers: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of the coccidiosis challenge, up to 480 mg monensin per head per day. Treat for not more than 5 days, then continue feeding monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xx) 400 to 2,000 g/ton	Monensin, 10 to 200.	Beef calves 2 months of age and older: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 1.00 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 200 mg of monensin per head per day. Feed for not more than 5 days, then continue to feed monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
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* * * * *

■ 37. In § 558.258, add paragraphs (e)(3)(iv)(A)(*3*) and (*4*) to read as follows:

§ 558.258 Fenbendazole.

(e) * * *

(3) * * *

(iv) * * *

(A) * * *

Fenbendazole concentration	Indications for use	Limitations	Sponsor
*	*	*	*
(*3*) 750 mg/lb of protein block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 16 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.	000061
(*4*) 750 mg/lb of molasses block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 11 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.	000061

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■ 38. In § 558.330, revise paragraphs (a) and (d)(1)(ii) and (iii) to read as follows:

§ 558.330 Lubabegron.

(a) *Specifications.* Each pound of Type A medicated article contains 4.54 grams (10 grams per kilogram) or 22.7 grams (50 grams per kilogram) of lubabegron as lubabegron fumarate.

* * * * *

(d) * * *

(1) * * *

Lubabegron fumarate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 1.25 to 4.54	Monensin, 5 to 40.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198

Lubabegron fumarate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 1.25 to 4.54	Monensin, 10 to 40.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198
*	*	*	*	*

■ 39. In § 558.355, redesignate paragraphs (f)(1)(iv), (v), and (vi) through (x) as paragraphs (f)(1)(vi), (vii), and (x) through (xiv), respectively, and add new paragraphs (f)(1)(iv), (v), (viii), and (ix) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(iv) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration throughout the feeding period. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in § 510.600(c) of this chapter.	069254
(v) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50.	Laying hen replacement chickens and layer breeder replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration throughout the feeding period. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in § 510.600(c) of this chapter.	069254
*	*	*	*	*
(viii) 90 to 110	Bacitracin methylenedisalicylate, 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*.	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in § 510.600(c) of this chapter.	069254
(ix) 90 to 110	Bacitracin methylenedisalicylate, 50.	Laying hen replacement chickens and layer breeder replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*.	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in § 510.600(c) of this chapter.	069254

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * *	* * *	* * *	* * *	

* * * * *

■ 40. In § 558.364, add paragraph (d)(2)(ii) to read as follows:

§ 558.364 Naracin and nicarbazin.

* * * * *

(d) * * *

(2) * * *

(ii) Virginiamycin as in § 558.635.

■ 41. In § 558.366, revise paragraph (d)(1)(i) and add paragraph (d)(2) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(d) * * *

(1) * * *

Nicarbazin in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 90.8 to 181.6	.....	Chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
* * *	* * *	* * *	* * *	

(2) Nicarbazin single-ingredient Type A medicated articles may also be used in combination with:

(i) [Reserved]

(ii) Virginiamycin as in § 558.635.

■ 42. In § 558.450:

■ a. Revise paragraph (e)(3)(i);

■ b. Redesignate paragraph (e)(3)(ii) as paragraph (e)(3)(iii); and

■ c. Add new paragraph (e)(3)(ii).

The revision and addition read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(3) * * *

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	.....	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days.	066104 069254
(ii) 10 mg/lb of body weight daily.	.....	Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 days.	066104 069254
* * *	* * *	* * *	* * *	

* * * * *

■ 43. In § 558.625, revise paragraphs (e)(2)(vii) and (viii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
* * *	* * *	* * *	* * *	
(vii) 8 to 10	Monensin, 5 to 40 plus lubabegron fumarate, 1.25 to 4.54.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(viii) 8 to 10	Monensin, 10 to 40 plus lubabegron fumarate, 1.25 to 4.54.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, up to 480 mg/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198
*	*	*	*	*

■ 44. In § 558.635, redesignate paragraphs (e)(1)(vii) through (ix) as paragraphs (e)(1)(ix) through (xi), respectively, and add new paragraphs (e)(1)(vii) and (viii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(1) * * *

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	*	*
(vii) 20	Narasin, 54 to 90	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Feed as the sole ration for broiler chickens. Do not feed to chickens producing eggs for human consumption. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Naracin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(viii) 20	Narasin, 27 to 54 plus nicarbazin, 27 to 54.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Feed as the sole ration for broiler chickens. Do not feed to chickens producing eggs for human consumption. Nicarbazin medicated broilers may show reduced heat tolerance if exposed to high temperature and high humidity. Provide adequate drinking water and ventilation during these periods. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Naracin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
*	*	*	*	*

* * * * *

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03649 Filed 3–9–23; 8:45 am]

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NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

RIN 3142–AA12

Representation Case Procedures

AGENCY: National Labor Relations Board.

ACTION: Final rule.

SUMMARY: This final rule rescinds four provisions from the Board's Rules and Regulations contained in the final rule published on December 18, 2019, entitled ''Representation-Case Procedures.'' This action is in compliance with a decision of the United States Court of Appeals for the District of Columbia Circuit vacating the four provisions.

DATES: This rule is effective March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half St. SE, Washington, DC 20570–0001, (202) 273–2940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION: On December 18, 2019, the National Labor Relations Board published a final rule amending various aspects of its representation case procedures. (84 FR 69524, Dec. 18, 2019.) The Board published the Final Rule as a procedural rule ''exempt from notice and public comment, pursuant to 5 U.S.C. 553(b)(3)(A), as a rule of 'agency organization, procedure, or practice.' '' 84 FR at 69587. On March 30, 2020, the Board delayed the effective date of the final rule to May 31, 2020. (85 FR 17500, Mar. 30, 2020.)

On May 30, 2020, the United States District Court for the District of Columbia issued an order in *AFL–CIO* v. *NLRB,* Civ. No. 20–cv–0675, vacating five provisions of the Final Rule and enjoining their implementation. 466 F. Supp. 3d 68 (D.D.C. 2020). The District Court concluded that each of the five provisions was substantive in nature, not procedural, and therefore required notice and comment rulemaking prior to promulgation under the Administrative Procedure Act. Id. at 92.

On January 17, 2023, the United States Court of Appeals for the District of Columbia Circuit issued a decision and order affirming the District Court as to three of the five provisions. *AFL–CIO* v. *NLRB,* 57 F.4th 1023, 2023 U.S. App. LEXIS 990 (D.C. Cir. Jan. 17, 2023). The three provisions that remain vacated are: (1) amendments to 29 CFR 102.62(d) and 102.67(l) giving employers up to 5 business days to furnish the voter list following the direction of election; [1] (2) an amendment to 29 CFR 102.69(a)(5) limiting a party's selection of election observers to individuals who are current members of the voting unit whenever possible; [2] and (3) an amendment to 29 CFR 102.69(b), (c), and (h) precluding Regional Directors from issuing certifications following elections if a request for review is pending or before the time has passed during which a request for review could be filed.[3]

The Court of Appeals also found that a fourth amendment, located at 29 CFR 102.67(c), (h), and (i)(3),[4] imposing an automatic impoundment of ballots under certain circumstances when a petition for review was pending with the Board, was contrary to Section 3(b) of the National Labor Relations Act. 57 F.4th 1023, 2023 U.S. App. LEXIS 990, at *59–*64. It accordingly vacated that portion of the Final Rule. *Id.* at *65.[5]

The Board is promulgating this rule to remove references in the regulations to the four provisions set aside and vacated by the Court of Appeals' decision and to revert the language of the regulations amended by the 2019 Final Rule to that which existed prior to the Final Rule as necessary to comply with the Court's decision. This rule is not subject to the requirement to provide notice and an opportunity for public comments because it falls under the good cause exception at 5 U.S.C. 553(b)(B). The good cause exception is satisfied when notice and comment is ''impracticable, unnecessary, or contrary to the public interest.'' Id. The four provisions of the 2019 Final Rule identified above have already been vacated by a court of law and no party has sought further review. This rule is simply an administrative step that reverts the language of the relevant regulations to their pre-2019 versions, to reflect the court order vacating those four provisions of the 2019 Final Rule.[6]

Additionally, because this rule implements a court order, the Board has good cause to waive the 30-day effective date under 5 U.S.C. 553(d). It would be contrary to the public interest to fail to keep the public informed of the accurate state of the Board's rules and regulations, especially now that these provisions have been ruled upon by the D.C. Circuit. See *Action on Smoking & Health* v. *Civil Aeronautics Bd.,* 713 F.2d 795, 797 (D.C. Cir. 1983) (judgment of court vacating rule ''had the effect of reinstating the rules previously in force''); *Mobil Oil Corp.* v. *EPA,* 35 F.3d 579, 584 (D.C. Cir. 1994) (same); see also Administrative Conference of the United States, *Improving Notice of Regulatory Changes, https://www.acus.gov/recommendation/improving-notice-regulatory-changes* (June 16, 2022); 5 U.S.C. 552(a)(1)(D), (E) (reading-room requirements under FOIA). In addition, it is unnecessary to take public comment on provisions that the D.C. Circuit has vacated.

Dissenting Opinion of Member Kaplan

In 2019, the Board issued a final rule [7] amending certain provisions of its representation-case rules, which had been extensively modified in a final rule enacted in 2014.[8] It did so without first issuing a notice of proposed rulemaking because it deemed the amendments rules of agency procedure exempt from notice-and-comment requirements under 5 U.S.C. 553(b)(3)(A). The AFL–CIO challenged the 2019 Rule in Federal District Court for the District of Columbia on several grounds, including that five provisions of the 2019 Rule were not procedural and therefore not exempt from notice-and-comment rulemaking. The district court agreed with the AFL–CIO and vacated all five.[9] Recently, a divided Court of Appeals for the District of Columbia Circuit (''D.C. Circuit'') reversed in part, holding that two of the five are procedural but three are not.[10] ''Those three provisions,'' said the court, ''must remain vacated unless and until the Board repromulgates them with notice and comment.'' [11] In dissent, Judge Rao said that the majority had applied an ''obsolete legal standard'' and that ''[u]nder the correct standard,'' all five ''are classic procedural rules.'' [12]

My colleagues have decided not to ask the Solicitor General to file a petition for certiorari with the Supreme Court. I dissented from their decision. The court's decision turned on its interpretation of what the controlling legal test should be for determining when rulemaking is procedural and therefore exempt from notice-and-comment requirements under the Administrative Procedure Act. Given that the D.C. Circuit is often the venue for cases involving federal rulemaking, all federal agencies that engage in rulemaking would be well served to have the Supreme Court decide whether the standard applied by the court in this matter was the appropriate test. Accordingly, unlike my colleagues, I consider this to be ''an important question of federal law that has not been, but should be, settled by'' the Supreme Court.[13]

That leaves the other possibility the court pointed out: repromulgating the three vacated provisions of the 2019 Rule in a notice of proposed rulemaking. But from my colleagues' rule rescinding those provisions,[14] you

[1] 84 FR at 69590, 69596–69597.

[2] 84 FR at 69597.

[3] 84 FR at 69597–69599.

[4] 84 FR at 69595–96.

[5] After careful consideration, the Board has decided not to seek rehearing or further review of the decision of the Court of Appeals. We note that the decision does not present a colorable conflict with the decision of another Circuit or with Supreme Court precedent. Nor do we believe that pursuing further litigation would represent the best use of the Board's resources or serve any overriding purpose of the National Labor Relations Act.

[6] Member Kaplan dissents from this final rule because he would issue a notice of proposed rulemaking for the three provisions that the Court of Appeals concluded were improperly promulgated without notice and comment, rather than rescind them. In our opinion, however, the Board's first priority should be to rescind the vacated rules so that the Board's rules and regulations accurately state agency practices in light of the Court's decision, regardless of whether the rules should be proposed again with notice and comment. Doing so promotes clarity for the benefit of parties before the Board who have to follow the rules as they existed prior to 2020, which the Court's decision implicitly reinstates and which we explicitly reinstate now.

In dissenting from our repeal of the fourth vacated provision, the impoundment rule, Member Kaplan does not suggest that the Court's opinion that the impoundment rule is inconsistent with Sec. 3(b) of the Act is appropriate for Supreme Court review, and he acknowledges that the Board could not reissue it under the Court's decision.

[7] ''Representation-Case Procedures,'' 84 FR 69524 (Dec. 18, 2019) (the ''2019 Rule'').

[8] ''Representation-Case Procedures,'' 79 FR 74307 (Dec. 15, 2014) (the ''2014 Rule'').

[9] *AFL–CIO* v. *NLRB,* 466 F. Supp. 3d 68 (D.D.C. 2020).

[10] *AFL–CIO* v. *NLRB,* 57 F.4th 1023, 2023 U.S. App. LEXIS 990, at *22–*56 (D.C. Cir. Jan. 17, 2023).

[11] Id. at *64–*65.

[12] Id. at *65–*66 (Rao, J., concurring in the judgment in part and dissenting in part).

[13] Supreme Court Rule 10(c).

[14] The D.C. Circuit majority also vacated a fourth provision of the 2019 Rule, which mandated

Continued

would not know that this is even an option. ''This rule,'' my colleagues say, ''is simply an administrative step that reverts the language of the relevant regulations to reflect the court order vacating'' them, adding that their rulemaking is ''necessary to comply with the Court's decision.'' It is clear, however, that rescinding the three provisions is *not* ''necessary to comply with the Court's decision.'' As the D.C. Circuit made clear, there is another option: repromulgating the three provisions in a notice of proposed rulemaking and inviting public comment. The Board should pursue that option. Accordingly, I dissent.

The three provisions at issue are these: (1) a rule providing that the employer must file and serve a list of eligible voters within 5 business days of the regional director's approval of an election agreement or issuance of a decision and direction of election (the ''voter-list rule''); (2) a rule providing that, in their choice of individuals to serve as election observers, the parties shall select, whenever possible, current members of the voting unit, and when this is not possible, a party should select a current nonsupervisory employee (the ''election-observers rule''); and (3) a rule providing that the regional director will only issue a certification of the results of an election—including, where appropriate, a certification of representative—after the deadline for filing a request for review of a decision and direction of election has passed without such a request being filed, and if a request for review is timely filed, the certification will issue only after the Board has ruled on that request (the ''certification-timing rule'').

The voter-list rule and the certification-timing rule amended corresponding provisions of the 2014 Rule, and the Board set forth persuasive reasons for doing so. The election-observers rule did not amend a provision of the 2014 Rule but rather was promulgated to bring transparency and uniformity to an area of Board law that was ''riddled with inconsistencies.'' 84 FR 69552. I believe, subject to comments, that each of these provisions in the 2019 Rule should be preserved. In my view, therefore, the Board should propose readopting them in a notice of proposed rulemaking and invite public comment.[15]

The voter-list rule: Prior to the 2014 Rule, an employer's duty to furnish a list of eligible voters was governed by *Excelsior Underwear, Inc.,* 156 NLRB 1236 (1966). Under that precedent, an employer was required to file with the regional director a list of the names and addresses of employees eligible to vote in an upcoming representation election within 7 calendar days after the regional director approved an election agreement or issued a decision and direction of election. Id. at 1239–1240. The 2014 Rule shrank 7 calendar days to 2 business days and added a number of other requirements, including by requiring the employer to furnish employees' personal email addresses and home and cellphone numbers. The 2019 Rule left most of those additional requirements intact, but it increased the amount of time the employer has to furnish the voter list from 2 business days to 5 business days.

The Board's explanation of its reasons for making this change was thorough and persuasive.

First, the main reason the 2014 Rule cut the time to 2 business days—namely, to speed the election—was no longer a relevant consideration. Under another provision of the 2019 Rule—one the D.C. Circuit agreed was procedural and therefore did not require notice and comment—regional directors will not normally schedule an election before the 20th business day following issuance of the decision and direction of election. Accordingly, directed elections will not take place any sooner with the 2-day deadline imposed by the 2014 Rule than with a 5-day deadline. And while this rationale is only pertinent to directed elections, applying the same 5-day deadline for all elections, including those conducted pursuant to stipulated election agreements, promotes uniformity.

Second, the Board's 2019 Rule stated several reasons why allowing employers 5 business days to furnish the voter list is superior as a matter of policy to allotting just 2 business days. To begin with, although technological changes since *Excelsior Underwear* make it easier for some employers to compile the necessary information rapidly, this is not the case for all employers. The information may not be computerized, or it may be kept in multiple locations. Assembling the voter list can be challenging for large or decentralized employers, and it may pose special problems for employers in the construction industry, where the Board's voter-eligibility formula is based on the fact that employment in that industry is often sporadic.[16] Moreover, one of the reasons stated in the 2014 Rule for the 2-day deadline raised questions of transparency and fairness. There, the Board justified the 2-day limit partly on the basis that employers may begin assembling the voter list before the regional director approves the election agreement or issues the decision and direction of election. The Board criticized this rationale in the 2019 Rule, and justly so. No duty to assemble the voter list attaches *until* the election agreement is approved or the decision and direction issues. ''It is anything but transparent,'' the Board observed, ''to state that a procedural requirement attaches at a certain point yet defend a truncated timeline for meeting that requirement by opining that employers have ample time to comply with the requirement before it has even attached to begin with.'' 84 FR 69532. I agree.

Finally, giving employers three more days to compile the voter list reduces the potential for inaccurate lists. And because an unacceptably incomplete list is grounds to set aside the results of an election, reducing the potential for inaccuracy also reduces litigation and resulting costs for the parties and the Agency.

For these reasons and those set forth more fully in the 2019 Rule, the Board should repromulgate the voter-list rule in a notice of proposed rulemaking.

The election-observers rule: The Board should do likewise with the election-observers rule.

Beginning in 1946, the Board's Rules and Regulations broadly provided that ''[a]ny party may be represented by observers of [its] own selection, subject to such limitations as the Regional Director may prescribe.'' 11 FR 177A–602–612 (Sept. 11, 1946). Thereafter, however, the Board imposed certain limitations decisionally. Employers may

impoundment of ballots if a request for review of a regional director's decision and direction of election is filed within 10 days of issuance of the decision and direction. The court held this provision unlawful as contrary to Sec. 3(b) of the Act. Interpreting Sec. 3(b) differently than the majority, Judge Rao would have upheld this provision as well. Although I agree with Judge Rao's interpretation, I recognize that repromulgating the ballot-impoundment provision for notice and comment is not an option.

[15] The following remarks summarize more detailed discussions of these three provisions in the 2019 Rule itself. For the voter-list rule, see 84 FR 69531–69532. For the election-observers rule, see 84 FR 69551–69553. For the certification-timing rule, see 84 FR 69554–69556.

[16] Under the *Steiny-Daniel* eligibility formula applicable to employers in the construction industry, employees eligible to vote in a representation election include (a) those employed by the employer during the payroll period immediately preceding the date of the decision and direction of election, and (b) those employed by the employer for a total of 30 working days in the preceding 12 months or 45 working days in the preceding 24 months. See *Steiny & Co.,* 308 NLRB 1323 (1992), and *Daniel Construction Co.,* 133 NLRB 264 (1961), modified at 167 NLRB 1078 (1967). It is self-evident why a construction-industry employer may be hard pressed to compile a list of eligible voters under the *Steiny/Daniel* formula in just 2 days.

not use individuals closely identified with management.[17] Unions may not use supervisors,[18] and they may not use nonemployee union officials in decertification elections.[19] The Board encouraged the use of nonsupervisory employees,[20] and a past edition of its Casehandling Manual even mandated this practice, declaring that absent written agreement, the parties *must* use nonsupervisory employees of the employer as election observers.[21] Moreover, even though the standard wording of stipulated election agreements provides for the parties to station equal numbers of ''nonsupervisory-employee observers'' at the polls, Board precedent since 1993 had held that it was not a material breach of the agreement for the union to use a nonemployee.[22]

Because Board law concerning the selection of observers was ''riddled with inconsistencies,'' 84 FR 69552, the Board included a new election-observers provision in the 2019 Rule. The rule provided that any party may be represented by observers of its own selection; that whenever possible, a party ''shall'' select a current member of the voting unit; and that, when no such individual is available, a party ''should'' select a current nonsupervisory employee. To effectively overrule precedent permitting unions to use their agents (who are employees *of the union*) as observers, the Board also clarified that (a) the ''nonsupervisory-employee'' wording of the standard election agreement refers to nonsupervisory employees of the employer that is party to the election, and (b) any use of an observer not employed by that employer is a material breach of the election agreement.

The Board justified the election-observers rule on several grounds. It promotes transparency by codifying the historical preference for using nonsupervisory employees as observers. It further promotes transparency by making clear that this preference applies to *any* party, not just to employers as certain decisions had suggested. It promotes uniformity by setting forth a clear framework under which all parties select their observers. And it promotes efficiency by eliminating wasteful litigation over the identity of election observers.

These are sound justifications for a sound rule. Rather than rescind it as my colleagues have done, the better course would be for the Board to repromulgate it in a notice of proposed rulemaking and invite public comment.

The certification-timing rule: Before the 2014 Rule issued, regional directors issued certifications of election results—including, where appropriate, certifications of representative—only in limited circumstances. Under the 2014 Rule, they were effectively required to do so in almost all cases. Moreover, they were required to do so regardless of whether a request for review of the decision and direction of election remained pending or the time within which to file a request for review had not yet elapsed. As a result, a union would be certified as the representative of a bargaining unit, even though a pending or yet-to-be-filed request for review could result in the certification being vacated. This could have untoward consequences, especially for employers, since the duty to bargain attaches when the union is certified. Thus, under the 2014 Rule, an employer could be found to have violated Section 8(a)(5) by refusing to bargain, at a time when its pending or to-be-filed request for review could yet result in the union's representative status being undone.[23]

To fix this state of affairs, the 2019 Rule specified that regional directors will only issue certifications after the time for filing a request for review has passed without any request being filed, and that, if a request for review is filed, certification will issue only after the Board rules on the request. The Board provided several justifications for this certification-timing rule. It ''advances transparency by eliminating confusion and complications occasioned by certifications that issue prior to the Board's ruling on a request for review.'' 84 FR 69554. It promotes finality, since the duty to bargain will attach only after the Board has ruled on a request for review or the time for filing one has passed. And since the Board's ruling on a request for review may nullify a previously issued certification, waiting to issue the certification until after the Board rules ''is a far more orderly way of proceeding'' and thus promotes efficiency. 84 FR 69555.

For these reasons and all the reasons stated more fully in the 2019 Rule, the certification-timing rule makes eminent sense—far better sense than the 2014–Rule framework it replaced. I would not rescind it as my colleagues do, but rather repromulgate it—and with it, the voter-list and election-observers rules—for notice-and-comment rulemaking.

List of Subjects in 29 CFR Part 102

Administrative practice and procedure, Labor management relations.

For the reasons stated in the preamble, the National Labor Relations Board amends 29 CFR part 102 as follows:

PART 102—RULES AND REGULATIONS, SERIES 8

■ 1. The authority citation for part 102 continues to read as follows:

Authority: Sections 1, 6, National Labor Relations Act (29 U.S.C. 151, 156). Section 102.117 also issued under section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)), and § 102.117a also issued under section 552a(j) and (k) of the Privacy Act of 1974 (5 U.S.C. 552a(j) and (k)). Sections 102.143 through 102.155 also issued under section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

■ 2. In § 102.62, revise paragraph (d) to read as follows:

§ 102.62 Election agreements; voter list; Notice of Election.

* * * * *

(d) *Voter list.* Absent agreement of the parties to the contrary specified in the election agreement or extraordinary circumstances specified in the direction of election, within 2 business days after the approval of an election agreement pursuant to paragraph (a) or (b) of this section, or issuance of a direction of election pursuant to paragraph (c) of this section, the employer shall provide to the Regional Director and the parties named in the agreement or direction a list of the full names, work locations, shifts, job classifications, and contact information (including home addresses, available personal email addresses, and

[17] See, *e.g., Peabody Engineering Co.,* 95 NLRB 952, 953 (1951).

[18] See *Family Service Agency,* 331 NLRB 850 (2000).

[19] See *Butera Finer Foods, Inc.,* 334 NLRB 43 (2001).

[20] See id.; *Jat Transportation Corp.,* 131 NRLB 122, 126 (1961).

[21] CHM Sec. 11310 (1989).

[22] See *Embassy Suites Hotel,* 313 NLRB 302 (1993); cf. *E–Z Davies Chevrolet,* 161 NLRB 1380, 1382–1383 (1966) (rejecting employer's contention that the presence of a union agent not employed by the employer as an election observer constituted objectionable conduct), enfd. 395 F.2d 191 (9th Cir. 1968).

[23] It was even possible that an unfair labor practice charge and the underlying representation case on which the charge was based could end up pending before the Board *at the same time.* This would happen if the employer refused to bargain while its request for review remained pending, the certified union filed an unfair labor practice charge, and the region issued complaint and moved for summary judgment. The Board acknowledged in the 2019 Rule that this scenario was ''largely hypothetical,'' given that regional directors typically held such charges in abeyance until the Board ruled on the request for review. 84 FR 69555. Nevertheless, the 2014 Rule allowed for this—and the regional directors' practical solution to the problem the 2014 Rule created was problematic in another respect, since it meant delaying vindication of the union's rights.

available home and personal cellular ''cell'' telephone numbers) of all eligible voters. The employer shall also include in separate sections of that list the same information for those individuals who will be permitted to vote subject to challenge. In order to be timely filed and served, the list must be received by the Regional Director and the parties named in the agreement or direction respectively within 2 business days after the approval of the agreement or issuance of the direction unless a longer time is specified in the agreement or direction. The list of names shall be alphabetized (overall or by department) and be in an electronic format approved by the General Counsel unless the employer certifies that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the Regional Director and served electronically on the other parties named in the agreement or direction. A certificate of service on all parties shall be filed with the Regional Director when the voter list is filed. The employer's failure to file or serve the list within the specified time or in proper format shall be grounds for setting aside the election whenever proper and timely objections are filed under the provisions of § 102.69(a)(8). The employer shall be estopped from objecting to the failure to file or serve the list within the specified time or in the proper format if it is responsible for the failure. The parties shall not use the list for purposes other than the representation proceeding, Board proceedings arising from it, and related matters.

* * * * *

■ 3. In § 102.67, revise paragraphs (c), (h), (i)(3), and (l) to read as follows:

§ 102.67 Proceedings before the Regional Director; further hearing; action by the Regional Director; appeals from actions of the Regional Director; statement in opposition; requests for extraordinary relief; Notice of Election; voter list.

* * * * *

(c) *Requests for Board review of Regional Director actions.* Upon the filing of a request therefor with the Board by any interested person, the Board may review any action of a Regional Director delegated to him/her under Section 3(b) of the Act except as the Board's Rules provide otherwise, but such a review shall not, unless specifically ordered by the Board, operate as a stay of any action by the Regional Director. The request for review may be filed at any time following the action until 10 business days after a final disposition of the proceeding by the Regional Director. No party shall be precluded from filing a request for review of the direction of election within the time provided in this paragraph because it did not file a request for review of the direction of election prior to the election.

* * * * *

(h) *Grant of review; briefs.* The grant of a request for review shall not stay the Regional Director's action unless otherwise ordered by the Board. Except where the Board rules upon the issues on review in the order granting review, the appellants and other parties may, within 10 business days after issuance of an order granting review, file briefs with the Board. Such briefs may be reproductions of those previously filed with the Regional Director and/or other briefs which shall be limited to the issues raised in the request for review. No reply briefs may be filed except upon special leave of the Board. Where review has been granted, the Board may provide for oral argument or further hearing. The Board will consider the entire record in the light of the grounds relied on for review and shall make such disposition of the matter as it deems appropriate. Any request for review may be withdrawn with the permission of the Board at any time prior to the issuance of the decision of the Board thereon.

(i) * * *

(3) *Extensions.* Requests for extensions of time to file requests for review, statements in opposition to a request for review, or briefs, as permitted by this section, shall be filed pursuant to § 102.2(c) with the Board or the Regional Director, as the case may be. The party filing the request for an extension of time shall serve a copy thereof on the other parties and, if filed with the Board, on the Regional Director. A statement of such service shall be filed with the document.

* * * * *

(l) *Voter list.* Absent extraordinary circumstances specified in the direction of election, the employer shall, within 2 business days after issuance of the direction, provide to the Regional Director and the parties named in such direction a list of the full names, work locations, shifts, job classifications, and contact information (including home addresses, available personal email addresses, and available home and personal cellular ''cell'' telephone numbers) of all eligible voters. The employer shall also include in separate sections of that list the same information for those individuals who will be permitted to vote subject to challenge. In order to be timely filed and served, the list must be received by the Regional Director and the parties named in the direction respectively within 2 business days after issuance of the direction of election unless a longer time is specified therein. The list of names shall be alphabetized (overall or by department) and be in an electronic format approved by the General Counsel unless the employer certifies that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the Regional Director and served electronically on the other parties named in the direction. A certificate of service on all parties shall be filed with the Regional Director when the voter list is filed. The employer's failure to file or serve the list within the specified time or in proper format shall be grounds for setting aside the election whenever proper and timely objections are filed under the provisions of § 102.69(a)(8). The employer shall be estopped from objecting to the failure to file or serve the list within the specified time or in the proper format if it is responsible for the failure. The parties shall not use the list for purposes other than the representation proceeding, Board proceedings arising from it, and related matters.

■ 4. In § 102.69, revise paragraphs (a)(5), (b), (c)(1)(i) and (iii), (c)(2), and (h) to read as follows:

§ 102.69 Election procedure; tally of ballots; objections; certification by the Regional Director; hearings; Hearing Officer reports on objections and challenges; exceptions to Hearing Officer reports; Regional Director decisions on objections and challenges.

(a) * * *

(5) When the election is conducted manually, any party may be represented by observers of its own selection, subject to such limitations as the Regional Director may prescribe.

* * * * *

(b) *Certification in the absence of objections, determinative challenges and runoff elections.* If no objections are filed within the time set forth in paragraph (a)(8) of this section, if the challenged ballots are insufficient in number to affect the results of the election, and if no runoff election is to be held pursuant to § 102.70, the Regional Director shall forthwith issue to the parties a certification of the results of the election, including certification of representative where appropriate, with the same force and effect as if issued by the Board.

(c) *Regional director's resolution of objections and challenges*—(1) *Regional director's determination to hold a hearing*—(i) *Decisions resolving*

objections and challenges without a hearing. If timely objections are filed to the conduct of an election or to conduct affecting the results of the election, and the Regional Director determines that the evidence described in the accompanying offer of proof would not constitute grounds for setting aside the election if introduced at a hearing, and the Regional Director determines that any determinative challenges do not raise substantial and material factual issues, the Regional Director shall issue a decision disposing of the objections and determinative challenges, and a certification of the results of the election, including certification of representative where appropriate.

* * * * *

(iii) *Hearings; Hearing Officer reports; exceptions to Regional Director.* The hearing on objections and challenges shall continue from day to day until completed unless the Regional Director concludes that extraordinary circumstances warrant otherwise. Any hearing pursuant to this section shall be conducted in accordance with the provisions of §§ 102.64, 102.65, and 102.66, insofar as applicable. Any party shall have the right to appear at the hearing in person, by counsel, or by other representative, to call, examine, and cross-examine witnesses, and to introduce into the record evidence of the significant facts that support the party's contentions and are relevant to the objections and determinative challenges that are the subject of the hearing. The Hearing Officer may rule on offers of proof. Any party desiring to submit a brief to the Hearing Officer shall be entitled to do so within 5 business days after the close of the hearing. Prior to the close of the hearing and for good cause the Hearing Officer may grant an extension of time to file a brief not to exceed an additional 10 business days. Upon the close of such hearing, the Hearing Officer shall prepare and cause to be served on the parties a report resolving questions of credibility and containing findings of fact and recommendations as to the disposition of the issues. Any party may, within 10 business days from the date of issuance of such report, file with the Regional Director an original and one copy of exceptions to such report, with supporting brief if desired. A copy of such exceptions, together with a copy of any brief filed, shall immediately be served on the other parties and a statement of service filed with the Regional Director. Within 5 business days from the last date on which exceptions and any supporting brief may be filed, or such further time as the Regional Director may allow, a party opposing the exceptions may file an answering brief with the Regional Director. An original and one copy shall be submitted. A copy of such answering brief shall immediately be served on the other parties and a statement of service filed with the Regional Director. Extra copies of electronically-filed papers need not be filed. The Regional Director shall thereupon decide the matter upon the record or make other disposition of the case. If no exceptions are filed to such report, the Regional Director, upon the expiration of the period for filing such exceptions, may decide the matter forthwith upon the record or may make other disposition of the case.

(2) *Regional Director decisions and Board review.* The decision of the Regional Director disposing of challenges and/or objections may include a certification of the results of the election, including certification of representative where appropriate, and shall be final unless a request for review is granted. If a consent election has been held pursuant to §§ 102.62(a) or (c), the decision of the Regional Director is not subject to Board review. If the election has been conducted pursuant to § 102.62(b), or by a direction of election issued following any proceeding under § 102.67, the parties shall have the right to Board review set forth in § 102.67, except that in any proceeding wherein a representation case has been consolidated with an unfair labor practice proceeding for purposes of hearing and the election was conducted pursuant to §§ 102.62(b) or 102.67, the provisions of § 102.46 shall govern with respect to the filing of exceptions or an answering brief to the exceptions to the Administrative Law Judge's decision, and a request for review of the Regional Director's decision and direction of election shall be due at the same time as the exceptions to the Administrative Law Judge's decision are due.

* * * * *

(h) *Final Disposition.* For the purposes of filing a request for review pursuant to § 102.67(c) or to paragraph (c)(2) of this section, a case is considered to have reached final disposition when the Regional Director dismisses the petition or issues a certification of results (including, where appropriate, a certification of representative).

Dated: March 6, 2023.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2023–04840 Filed 3–9–23; 8:45 am]

BILLING CODE 7545–01–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

RIN 3142–AA12

Representation Case Procedures

AGENCY: National Labor Relations Board.

ACTION: Final rule; stay.

SUMMARY: The National Labor Relations Board (Board) is staying two provisions of its 2019 final rule (''Final Rule'') amending its representation case procedures to account for new court decisions. The two provisions, which have never been in effect, are stayed until September 10, 2023. This stay is necessary to accommodate pending litigation over remaining challenges to the Final Rule and because the Board is currently considering whether to revise or repeal the Final Rule, including potential revisions to the two provisions.

DATES: As of March 10, 2023, the amendments to 29 CFR 102.64(a) and 29 CFR 102.67(b) in the final rule that published at 84 FR 69524, on December 18, 2019, and delayed at 85 FR 17500, March 30, 2020, are stayed from May 31, 2020, until September 10, 2023.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half St. SE, Washington, DC 20570–0001, (202) 273–2940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION: On December 18, 2019, the National Labor Relations Board published a final rule amending various aspects of its representation-case procedures. (84 FR 69524, Dec. 18, 2019.) The Board published the Final Rule as ''a procedural rule which is exempt from notice and public comment, pursuant to 5 U.S.C. 553(b)(3)(A), as a rule of 'agency organization, procedure, or practice.' '' 84 FR at 69587. On March 30, 2020, the Board delayed the effective date of the final rule to May 31, 2020, upon request of the United States District Court for the District of Columbia and to ''facilitate the resolution of the legal challenges that have been filed with respect to the rule.'' (85 FR 17500, Mar. 30, 2020.)

On May 30, 2020, the United States District Court for the District of Columbia issued an order in *AFL–CIO* v. *NLRB,* Civ. No. 20–cv–0675, vacating five provisions of the Final Rule and enjoining their implementation. 466 F. Supp. 3d 68 (D.D.C. 2020). The District

Court concluded that each of the five provisions was substantive in nature, not procedural, and that the Board therefore violated the Administrative Procedure Act by failing to use notice and comment rulemaking. Id. at 92.

On January 17, 2023, the United States Court of Appeals for the District of Columbia Circuit issued a decision and order reversing the District Court as to two of the five provisions, agreeing with the Board that those provisions were procedural in nature and not subject to notice and comment rulemaking. *AFL–CIO* v. *NLRB,* 57 F.4th 1023, (D.C. Cir., 2023). The two provisions are: (1) an amendment to 29 CFR 102.64(a) allowing the parties to litigate disputes over unit scope and voter eligibility prior to the election; [1] and (2) an amendment to 29 CFR 102.67(b) instructing Regional Directors not to schedule elections before the 20th business day after the date of the direction of election.[2] The D.C. Circuit remanded the case to the District Court to consider two counts in the complaint that challenge these two provisions and that remain viable in light of its decision.

Due to the District Court's injunction, these two provisions have never taken effect. The time for filing a petition for rehearing with the D.C. Circuit under Federal Rule of Appellate Procedure 40 has passed, and, once the District of Columbia Circuit's mandate issues on or about March 10, 2023, the District Court's injunction will be lifted. At that point, the two previously enjoined provisions will go into effect pursuant to the original May 31, 2020 effective date. The District Court will also begin its consideration of the challenges to the two provisions remaining for decision.

The Board has decided to stay the effective date of the two provisions to September 10, 2023, six months from the expected issuance of the District of Columbia Circuit's mandate. The Board has determined that staying those provisions until September 10, 2023 would accommodate the pending legal challenges before the District Court. 5 U.S.C. 705. Moreover, a stay is necessary and appropriate because the Board is currently considering whether to revise or repeal the Final Rule, including potential revisions to these two provisions. Delayed implementation of these provisions will permit further consideration by the Board of the merits of the Final Rule and will avoid the possible waste of administrative resources and public uncertainty if the provisions were to go into effect only for a short period of time before being impacted by forthcoming revisions. The stay of the two provisions' effective date merely extends the status quo.

We disagree with the dissenting position of Member Kaplan, who argues a stay in the effective date of the two provisions is unwarranted. His position is based on his view of the policy merits of the provisions and the legal merits of the pending challenge to them in the District Court. At this juncture, however, consideration of the provisions' merits by the Board is premature. Resolution of the legal challenge to the provisions, in turn, is a matter for the District Court. As explained, a stay of the effective date of the provisions facilitates both processes, by preserving the status quo.

This stay is published as a final rule. The Board considers this rule to be a procedural rule that is exempt from notice and public comment, pursuant to 5 U.S.C. 553(b)(3)(A), because it concerns a rule of ''agency organization, procedure, or practice.'' *AFL–CIO* v. *NLRB,* 57 F.4th at 1035.

Dissenting Opinion of Member Kaplan

In 2019, the Board issued a final rule [1] amending certain provisions of its representation-case rules, which had been extensively modified in a final rule enacted in 2014.[2] It did so without first issuing a notice of proposed rulemaking because it viewed the amendments as pertaining to ''rules of agency . . . procedure,'' and such ''procedural rules'' are exempt from notice-and-comment requirements under 5 U.S.C. 553(b)(3)(A). The AFL–CIO challenged the 2019 Rule in the United States District Court for the District of Columbia on several grounds, including that five provisions of the 2019 Rule were not procedural and therefore not exempt from notice-and-comment rulemaking. The district court agreed with the AFL–CIO and vacated all five.[3] Recently, a divided Court of Appeals for the District of Columbia Circuit (''D.C. Circuit'' or ''court of appeals'') reversed in part, holding that two of the five are procedural but three are not.[4] ''Those three provisions,'' said the court, ''must remain vacated unless and until the Board repromulgates them with notice and comment.'' [5] In dissent, Judge Rao said that the majority had applied an ''obsolete legal standard'' and that ''[u]nder the correct standard,'' all five ''are classic procedural rules.'' [6]

In a separate final rule issued today, my colleagues rescind the three provisions of the 2019 Rule that the D.C. Circuit held to be not procedural. As I explain in my dissent to that rule, I would have asked the Solicitor General to file a petition for certiorari from the D.C. Circuit's decision because the controlling legal test for determining when rulemaking is procedural and therefore exempt from notice-and-comment requirements under the Administrative Procedure Act presents ''an important question of federal law that has not been, but should be, settled by'' the Supreme Court.[7] But since my colleagues did not join me in that regard, I would pursue the option the D.C. Circuit suggested and repromulgate the three provisions the court held not procedural for notice-and-comment rulemaking.[8] I would do so because I believe, subject to comments, that those three provisions are superior to the rules that my colleagues have snapped back into place.

In the instant final rule, the majority addresses the two provisions of the 2019 Rule that the D.C. Circuit held to be procedural and therefore properly implemented without notice and comment. The AFL–CIO's challenge to those two provisions was not limited to its claim that they are not procedural, but the district court, having vacated them (erroneously) as not procedural, did not address the AFL–CIO's remaining contentions. Accordingly, the D.C. Circuit remanded the two provisions to the district court to address those contentions. Meanwhile, because the D.C. Circuit has held that those two provisions *are* procedural and therefore were properly enacted without notice and comment, they will take effect when the court of appeals issues its mandate. To prevent that from happening, my colleagues issue this rule to stay the effective date of the two provisions to September 10, 2023.

[1] 84 FR at 69593.

[2] 84 FR at 69595.

[1] ''Representation-Case Procedures,'' 84 FR 69524 (Dec. 18, 2019) (the ''2019 Rule'').

[2] ''Representation-Case Procedures,'' 79 FR 74307 (Dec. 15, 2014) (the ''2014 Rule'').

[3] *AFL–CIO* v. *NLRB,* 466 F. Supp. 3d 68 (D.D.C. 2020).

[4] *AFL–CIO* v. *NLRB,* 57 F.4th 1023, 1034–1046 (D.C. Cir. 2023).

[5] Id. at 1049.

[6] Id. at 1050 (Rao, J., concurring in the judgment in part and dissenting in part).

[7] Supreme Court Rule 10(c).

[8] The D.C. Circuit also vacated a fourth provision of the 2019 Rule, which mandated impoundment of ballots if a request for review of a regional director's decision and direction of election is filed within 10 days of issuance of the decision and direction, and the Board has either granted or not ruled on the request for review before the conclusion of the election. The court held this provision unlawful as contrary to Sec. 3(b) of the Act. Interpreting Sec. 3(b) differently than the majority, Judge Rao would have upheld this provision as well. Although I agree with Judge Rao's interpretation, I recognize that repromulgating the ballot-impoundment provision for notice and comment is not an option.

I disagree with their decision to do so. My colleagues state two reasons for issuing this stay: to give the district court time to consider the AFL–CIO's remaining arguments on remand, and to give themselves time to decide whether to revise or repeal the 2019 Rule, including the two provisions that have been sent back to the district court. I will not take this occasion to mount a comprehensive defense of the 2019 Rule. There is not time for me to do so; the court of appeals will issue its mandate on March 10, and my colleagues are determined to issue this rule before that happens. I will, however, explain why the two provisions of the 2019 Rule at issue here should be allowed to take effect when the court issues its mandate.

The two provisions are these: (1) a rule providing that unit scope and voter eligibility (including supervisory status) normally will be litigated and resolved by the regional director before he or she directs the election (the ''unit-scope-and-eligibility rule''), and (2) a rule providing that normally, the regional director will not schedule an election before the 20th business day after the date of the direction of election (the ''20-days rule''). As the Board said in the 2019 Rule, these two provisions go hand in hand: the regional director will resolve disputes over unit scope and voter eligibility before directing the election, and the 20-days rule will give the Board time to act on a request for review of the regional director's decision if one is filed. They should be allowed to take effect when mandate issues for two reasons. They promote important interests that the 2014 Rule subordinated to speed. And there is no good reason to wait for the district court to rule on the AFL–CIO's remaining arguments for vacating these provisions because those arguments are meritless.

The rules at issue promote important interests.

Under the 2014 Rule, regional directors were instructed to schedule elections on ''the earliest date practicable,'' and litigation of disputes over unit scope and voter eligibility, including supervisory status, were largely postponed until after the election. Speed—*i.e.,* shortening the time between the filing of the representation petition and the election—was prioritized over other interests. In the 2019 Rule, the Board acknowledged that speed is an important interest and that some of the changes it was making to the Board's representation-case procedures would unavoidably result in some delay between the filing of the petition and the election. But the Board made clear that none of the changes had a *purpose* of delay but were being made to serve other important interests.

Specifically as to the provisions of the 2019 Rule at issue here, I cannot improve on the concise explanation the Board furnished there of the interests those rules serve. The italics are mine.

> By permitting the parties—where they cannot otherwise agree on resolving or deferring such matters—to litigate issues of unit scope and employee eligibility at the pre-election hearing, by expecting the Regional Director to resolve these issues before proceeding to an election, and by providing time for the Board to entertain a timely-filed request for review of the regional director's resolution prior to the election, the final rule promotes *fair and accurate voting* by ensuring that the employees, at the time they cast their votes, know the contours of the unit in which they are voting. Further, by permitting litigation of these issues prior to the election, instead of deferring them until after the election, the final rule removes the pendency of such issues as a barrier to reaching *certainty and finality of election results.* Under *the 2014 amendments,* such issues could linger on after the election for weeks, months, or even years before being resolved. This state of affairs plainly *did not promote certainty and finality.*
>
> Relaxing the timelines instituted by the 2014 amendments also promotes *transparency.* . . . Providing employees with more detailed knowledge of the contours of the voting unit, as well as resolving eligibility issues, self-evidently promotes transparency; leaving issues of unit scope and employee eligibility unresolved until after an election (absent agreement of the parties to do so) clearly does a disservice to transparency. Relatedly, resolving issues such as supervisory status before the election ensures that the parties know who speaks for management and whose actions during the election campaign could give rise to allegations of objectionable conduct or unfair labor practice charges.

84 FR at 69529. I agree that the unit-scope-and-eligibility rule and the 20-days rule serve these important interests, and I believe these interests outweigh the interest in speed. Since I can think of no other reason my colleagues might have for repealing these rules than once again promoting speed at the expense of certainty, finality, and transparency, I would not delay their effective date to provide time to consider taking that step.

The AFL–CIO's remaining arguments are meritless.

The other reason the majority gives for staying of the unit-scope-and-eligibility rule and the 20-days rule is to provide time for the district court to rule on remand concerning the AFL–CIO's remaining grounds of attack on those rules. The AFL–CIO contends that both provisions must be vacated as arbitrary and capricious, and that the 20-days rule must additionally be vacated as contrary to Section 3(b) of the Act. There is no good reason to wait for the district court to dispose of these contentions because they will not succeed.

Regarding the AFL–CIO's arbitrary-and-capricious attack, one need look no further than the D.C. Circuit's decision to see that it will fail. The AFL–CIO had also argued before the district court that the 2019 Rule as a whole was arbitrary and capricious. Affirming the district court's dismissal of that argument, the court of appeals wrote as follows:

> The Board gives a rational account of how the 2019 Rule advances interests apart from speed. For example, the Board adequately explains that the election-scheduling provision—which supplements the ''earliest date practicable'' language with a default minimum period of twenty business days—promotes transparency and uniformity by making the timing of elections more predictable for parties. *See* [84 FR] at 69,546. It also explains that the provision regarding pre-election litigation of voter eligibility, unit scope, and supervisory status could provide employee-voters with more complete information about ''who they are voting to join in collective bargaining.'' *Id.* at 69,541.[9]

In other words, in explaining why the district court correctly rejected the AFL–CIO's contention that the 2019 Rule as a whole was arbitrary and capricious, the D.C. Circuit singled out the very provisions that are now back before the district court to determine whether they are arbitrary and capricious. The court of appeals could not have sent a clearer signal to the lower court that any other resolution besides dismissal is out of the question.

The AFL–CIO's claim that the 20-days rule is also unlawful as contrary to Section 3(b) of the Act also fails. Section 3(b) relevantly provides:

> [U]pon the filing of a request therefor with the Board by any interested person, the Board may review any action of a regional director delegated to him under this paragraph, but such a review shall not, unless specifically ordered by the Board, operate as a stay of any action taken by the regional director.

29 U.S.C. 159(b). The clear language of this provision indicates that it is triggered only ''upon the filing of a request [for review of a regional director's action] . . . with the Board.'' Even assuming that the 20-days rule ''operate[s] as a stay'' of an action taken by the regional director—namely, tallying the ballots—this alleged ''stay'' is not triggered by the filing of any request for review with the Board. Rather, it results from the 20-days rule

[9] *AFL–CIO* v. *NLRB,* 57 F.4th at 1047.

itself. Section 3(b) does not speak to that delay.[10]

In sum, my colleagues have failed to provide a persuasive reason for staying the effective date of the unit-scope-and-eligibility and 20-days rules. I favor allowing these rules to take effect just as soon as the D.C. Circuit issues mandate. Accordingly, from the majority's final rule, I dissent.

Dated: March 6, 2023.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2023–04839 Filed 3–9–23; 8:45 am]

BILLING CODE 7545–01–P

[10] As stated above, the court of appeals found that the ballot-impoundment provision in the 2019 Rule is contrary to Sec. 3(b). That provision, however, is expressly triggered only when a party *files a request for review* within ten business days of the issuance of the direction of election and when certain other conditions are met.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0163]

RIN 1625–AA00

Safety Zone; Missouri River Mile Markers 175.5–176.5, Jefferson City, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters in the Missouri River at Mile Marker (MM) 175.5 to 176.5. The safety zone is needed to protect personnel, vessels, and the marine environment from all potential hazards associated with electrical line work. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective from March 13, 2023, until March 24, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0163 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MSTC Nathaniel Dibley, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2550, email *Nathaniel.D.Dibley@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of The Port Sector Upper Mississippi River
DHS Department of Homeland Security
FR Federal Register
MM Mile marker
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this temporary safety zone immediately to protect personnel, vessels, and the marine environment from potential hazards created by the electrical work and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the ongoing construction work.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Upper Mississippi River (COTP) has determined that potential hazards associated with electrical line work will be a safety concern for anyone operating or transiting within the Missouri River from MM 175.5–176.5. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while electrical line work is being conducted.

IV. Discussion of the Rule

Electrical line work will be occurring near MM 175.5–176.5 beginning March 13, 2023. The safety zone is designed to protect waterway users until work is complete.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in the size of the safety zone as conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on a safety zone located on the Missouri River at MM 175.5–176.5, near Jefferson City, MO. The Safety Zone is expected to be active only during the hours of 9 a.m. through 4 p.m., or only when work is being conducted, every day until March 24, 2023.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended,

requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone encompassing the width of the Upper Mississippi River at MM 139.5–139.2. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security Measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0163 to read as follows:

§ 165.T08–0163 Safety Zone; Missouri River, Mile Markers 175.5–176.5, Jefferson City, MO.

(a) *Location.* The following area is a safety zone: all navigable waters within Missouri Mile Markers (MM) 175.5–176.5.

(b) *Enforcement period.* This section will be subject to enforcement from March 13, 2023, through March 24, 2023.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone as ice or flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: March 3, 2023.

A.R. Bender,

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

[FR Doc. 2023–04865 Filed 3–9–23; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2021–0663; EPA–R02–OAR–2021–0673; EPA–R03–OAR–2021–0872; EPA–R03–OAR–2021–0873; EPA–R04–OAR–2021–0841; EPA–R05–OAR–2022–0006; EPA–R06–OAR–2021–0801; EPA–R07–OAR–2021–0851; EPA–R08–OAR–2022–0315; EPA–R09–OAR–2022–0394; EPA–R09–OAR–2022–0138; FRL–10209–02–OAR]

Air Plan Disapprovals; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that appeared in **Federal Register** on Monday, February 13, 2023, which finalized the disapproval of State Implementation Plan (SIP) submissions for 19 states and the partial approval and partial disapproval of elements of the SIP submission for two states regarding interstate transport obligations for the 2015 8-hour ozone national ambient air quality standards (NAAQS). This document corrects an error in an amendatory instruction that appeared in the regulatory text portion of the final rule. This error and its correction are unrelated to the final rule.

DATES: This correction is effective on March 15, 2023.

FOR FURTHER INFORMATION CONTACT: General questions concerning this document should be addressed to Mr. Thomas Uher, Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail Code C539–04, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number: (919) 541–5534; email address: *uher.thomas@epa.gov*.

SUPPLEMENTARY INFORMATION: The EPA is removing an unrelated amendatory instruction in its final rule, FRL–10209–01–OAR, published February 13, 2023 (88 FR 9336). Amendatory instruction 20 is corrected by removing instruction ''20a.'' and designating instruction ''20b.'' as the full instruction 20.

Correction

In FR Doc. 2023–02407, appearing on page 9336 in the **Federal Register** of Monday, February 13, 2023 (88 FR 9336), the following correction is made:

1. On page 9384, in the second column, amendatory instruction 20 is correctly revised to read as follows:

''20. Section 52.2275 is amended by adding paragraph (o) to read as follows:''.

Joseph Goffman,

Principal Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2023–04814 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2017–0355; FRL–10477–01–OAR]

RIN 2060–AV88

Delay of Submittal Date for State Plans Required Under the Affordable Clean Energy Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; delay of state plan submittal dates.

SUMMARY: This action extends until April 15, 2024, the deadline for state plans required to be submitted under the Clean Air Act (CAA) in accordance with the Affordable Clean Energy (ACE) rule.

DATES: This regulation is effective March 10, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2017–0355. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.*

FOR FURTHER INFORMATION CONTACT: For questions about this document contact Mr. Nicholas Swanson, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4080; email address: *swanson.nicholas@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA is taking this final action without providing an opportunity for public comment, based on the good cause exception in section 553(b)(3)(B) of the Administrative Procedure Act (APA). The Agency has determined that seeking public comment is impracticable, unnecessary, or contrary to the public interest. The deadline for state plan submission has already passed, which necessitates an extension, and it is important that the EPA grant that extension as soon as possible to avoid confusion and uncertainty among states and regulated industry as to what their obligations are.

I. Background and Extension of Deadlines

On July 8, 2019, the EPA promulgated the Affordable Clean Energy (ACE) rule, under CAA section 111(d) (84 FR 32520, July 8, 2019). The ACE rule is an emissions guideline that directs states to develop plans that establish standards of performance for carbon dioxide (CO_2) emissions from existing coal-fired electricity generating units. The ACE rule repealed and replaced the Clean Power Plan, which the EPA had promulgated in 2015 (80 FR 64662, October 23, 2015).

Under CAA section 111(d)(1), the standards of performance in such a state plan are required to achieve an amount of emission reduction that the EPA determines can be achieved through application by the sources of what the EPA determines to be the ''best system of emission reduction . . . adequately demonstrated'' (BSER) for reducing emissions of the pollutant in question from the sources in question. CAA section 111(a)(1). The ACE rule required states to submit plans to the EPA that establish standards of performance within three years of the date that the rule was published, that is, by July 8, 2022 (40 CFR 60.5745a).

Numerous state and municipal governments, power utilities, renewable energy trade associations, public health and environmental advocacy groups, and other parties filed petitions to review the ACE rule before the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit).

On January 19, 2021, following briefing and oral argument, the D.C. Circuit issued a decision vacating the ACE rule. *American Lung Ass'n* v. *EPA,* 985 F.3d 914 (D.C. Cir. 2021). The court based the vacatur on its holding that the ACE rule's underlying legal interpretation, which was that CAA

section 111(a)(1) and (d)(1) limited the BSER to control measures that can be applied at and to the source to reduce emissions at the source, is incorrect. *Id.* at 944–51. In light of this holding, the court did not find it necessary to address, and did not address, other legal and factual issues that petitioners raised concerning the ACE rule. The court issued a partial mandate concerning this part of its decision on March 5, 2021. *American Lung Ass'n* v. *EPA,* No. 19–1140, Order, Doc. Id. No. 1888579 (D.C. Cir. March 5, 2021).

On October 2021, the U.S. Supreme Court granted petitions for *certiorari* filed by several parties to the case, and, on June 30, 2022, issued a decision reversing the D.C. Circuit on other grounds. *West Virginia* v. *EPA,* 142 S.Ct. 2587 (2022). Specifically, the Court reversed the D.C. Circuit's vacatur of the ACE rule's repeal of the Clean Power Plan, holding that the Clean Power Plan was invalid under the major questions doctrine. *Id.* at 2615–16.

On October 27, 2022, the D.C. Circuit responded to the Supreme Court decision by issuing an order that, in relevant part, withdrew the above-noted mandate, thereby reinstating the ACE rule. Because the EPA had informed the court that it is presently undertaking a rulemaking process to replace the ACE rule with a new rule governing greenhouse gas emissions from existing fossil-fuel-fired power plants, the court placed the case in abeyance pending completion of that rulemaking, rather than proceed to consider the remaining factual and legal issues raised by petitioners with respect to the ACE rule.

Thus, the ACE rule was vacated for the last 536 days of the three-year period for state plan submittal, beginning on January 19, 2021, and extending through July 8, 2022. The rule remained vacated through October 26, 2022, and then was reinstated on October 27, 2022. Because the ACE rule has been reinstated, states are once again under an obligation to submit the state plans required under the rule. However, because the rule's July 8, 2022, deadline has passed, and because states had no reason to continue to work on their plans during the period when the ACE rule was vacated, it is necessary to extend the deadline for state plan submittal.

Accordingly, in this action, the EPA is extending the date of state plan submittal by 536 days from the October 27, 2022, reinstatement of the ACE rule. Thus, the ACE rule state plans are now due on April 15, 2024. As just noted, this 536-day period is the length of time that the ACE rule was vacated from the January 19, 2021, D.C. Circuit decision in *American Lung Ass'n* v. *EPA* to the rule's July 8, 2022, state plan submittal due date.

The EPA is taking this final action without providing an opportunity for public comment, based on the good cause exception in section 553(b)(3)(B) of the Administrative Procedure Act (APA). The Agency has determined that seeking public comment is impracticable, unnecessary, or contrary to the public interest. The deadline for state plan submission has already passed, which necessitates an extension, and it is important that the EPA grant that extension as soon as possible to avoid confusion and uncertainty among states and regulated industry as to what their obligations are. In addition, granting the extension as soon as possible is consistent with the public's interest in timely implementation of public health and environmental protections. See generally *Wisconsin* v. *EPA,* 933 F.3d 303, 312–20 (D.C. Cir. 2019) (invalidating EPA rule for granting upwind states a period of time that exceeded statutory limitations to reduce air pollutants that contribute significantly to air quality problems in downwind states). Although the ACE rule would achieve little emission reduction (85 FR 32561 & table 3) the extended deadline provides certainty to the public as to the timeline for submittal and implementation of state plans to achieve those reductions and preserves the original, three-year period for submittal as of the date of reinstatement of the rule.

Moreover, an extension equal to the number of days from when the ACE rule was vacated to the rule's submittal date is logical and is consistent with recent actions in which the D.C. Circuit granted a compliance date extension for a rule that had been stayed or vacated for a period of time. *Michigan* v. *EPA,* No. 98–1497, Order, Doc. Id. No. 540209 (D.C. Cir. Aug. 30, 2000) (extending the date for sources to implement state implementation plan (SIP) revisions required under EPA's NO_X SIP call rule by the number of days the D.C. Circuit had stayed the rule, so that sources will have the same number of days for developing the SIP revisions as provided in the original rule); ''Rulemaking To Amend Dates in Federal Implementation Plans Addressing Interstate Transport of Ozone and Fine Particulate Matter: Interim final rule with request for comment,'' 79 FR 71663 (December 3, 2014) (amending the Code of Federal Regulations to correctly reflect the deadlines for sources to comply with the Cross-State Air Pollution Rule, which deadlines were revised by the D.C. Circuit when it lifted the previous stay of the rule and, accordingly, delayed the compliance deadlines by three years).

For the same reasons, the EPA is also making today's action effective immediately upon publication in the **Federal Register**. Section 553(d) of the APA provides that rules generally may not take effect until 30 days after they are published in the **Federal Register**. The purpose of this APA provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when an agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. Thus, APA section 553(d) allows an effective date less than 30 days after publication for any rule that ''grants or recognizes an exemption or relieves a restriction'' (see 5 U.S.C. 553(d)(1)). An accelerated effective date may also be appropriate for ''good cause'' pursuant to APA section 553(d)(3) where an agency can ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Gavrilovic,* 551 F.2d at 1105. The EPA has determined that the state plan submittal date extension is effective upon publication because it relieves a restriction, thereby providing obligated parties with additional time to comply with the ACE rule's requirements. There is additionally good cause for immediate implementation of these requirements to avoid confusion and uncertainty among states and regulated industry regarding the timing of their compliance obligations.

It should be noted that the EPA has initiated a rulemaking process to repeal the ACE rule and replace it with another emissions guideline under CAA section 111(d) that would direct states to develop plans that establish standards of performance for CO_2 emissions from existing coal-fired electricity generating units. The EPA expects to propose this repeal and replacement rulemaking in the spring of 2023. If finalized, states would no longer be required to submit state plans to meet the requirements of ACE rule, and instead would be required to submit state plans to meet the requirements of the replacement emissions guideline, on the schedule established by that guideline.

II. Statutory and Executive Order Reviews

Additional information about these statutes and executive orders can be found at https://www.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. In this action, the EPA is extending the date of state plan submittal by the time that was lost due to the ACE rule being vacated. Any burden for information collection requests is consistent with the original ACE rule.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute a ''rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law. . . .'' 5 U.S.C. 601(2). The EPA is not publishing a notice of proposed rulemaking for this rule because it is invoking the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. In this action, the EPA is extending the date of state plan submittal by the time that was lost due to the ACE rule being vacated. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color) and low-income populations.

The EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. In this action, the EPA is extending the date of state plan submittal by the time that was lost due to the ACE rule being vacated.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

III. Statutory Authority

The statutory authority for this action is provided by sections 111, 301, and 302 of the CAA as amended (42 U.S.C. 7411, 7601, 7602). This action is also subject to section 553(b)(3)(B) of the APA (5 U.S.C. 553(b)(3)(B).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedures, Air pollution control, Reporting and recordkeeping requirements, Greenhouse gases.

Michael Regan,
Administrator.

For the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

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

Subpart UUUUa—Emission Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units

■ 2. Revise § 60.5745a to read as follows:

§ 60.5745a What are the timing requirements for submitting my plan?

You must submit a plan with the information required under § 60.5740a by April 15, 2024.

[FR Doc. 2023–04959 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–HQ–OAR–2022–0195; FRL–9631–01–OAR]

RIN 2060–AV66

Air Quality Redesignation for the 2008 Lead National Ambient Air Quality Standards; Canton, Ohio; Stark County, Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule redesignates a portion of Canton, Ohio in northeastern Stark County from ''unclassifiable/

attainment'' to ''nonattainment'' for the 2008 National Ambient Air Quality Standards (NAAQS) for lead (Pb). The EPA notified the state of Ohio of its intended redesignation of portions of Stark County on April 26, 2022, and published a Notice of Availability for this action on May 3, 2022. The EPA's redesignation of this portion of the Canton, Ohio area is based on recorded violations of the Pb NAAQS at the Republic Steel ambient air monitoring site operated by Ohio Environmental Protection Agency (Ohio EPA) located in Canton, Ohio.

DATES: This rule is effective on April 10, 2023.

ADDRESSES: The EPA has established a public docket for this redesignation action at *http://www.regulations.gov* under Docket ID No. EPA–HQ–OAR–2022–0195.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this action, please contact Andrew Leith, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail Code C539–01, Research Triangle Park, NC 27709, telephone number: (919) 541–1069, email address: *leith.andrew@epa.gov.* The following EPA Regional office contact can answer questions specific to the Canton, Ohio area: Alisa Liu of Region 5. She can be reached at telephone number: (312) 353–3193, email address: *liu.alisa@epa.gov* or address at EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

The EPA has established a website for the designations for the 2008 Pb NAAQS at *https://www.epa.gov/lead-designations.* The website includes the EPA's final redesignations action, technical support documents, and other related information.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA. The information in this document is organized as follows:

I. Background and Purpose of the EPA's Final Action
II. The 2008 Pb NAAQS
III. Clean Air Act Redesignation Authority
IV. The EPA's Redesignation Decision and Supporting Air Quality Information
A. Applicable Regulatory Provisions
B. Monitoring Network Considerations
C. Canton, Ohio Ambient Air Monitoring Site
D. Pb Data Considerations
E. Factors Considered in Determining Nonattainment Area Boundary
V. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act (PRA)
C. Regulatory Flexibility Act (RFA)
D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act (CRA)
L. Judicial Review
VI. Statutory of Authority

I. Background and Purpose of the EPA's Final Action

The purpose of this final action is to announce and promulgate the EPA's area redesignation of a portion of the Canton, Ohio area from ''unclassifiable/attainment'' to ''nonattainment'' for the 2008 Pb NAAQS. The EPA originally designated Stark County, Ohio, including the Canton area, along with the remaining areas of Ohio, as unclassifiable/attainment on November 8, 2011.[1]

After originally designating the Canton, Ohio area unclassifiable/attainment on November 8, 2011, the EPA determined in 2021 that quality-assured, certified monitoring data collected during 2017–2020 at the Ohio EPA ambient air monitoring site located at 3150 Georgetown Road NE in Canton, Ohio (Republic Steel ambient air monitoring site), showed that the area was violating the Pb NAAQS. Consistent with CAA section 107(d)(3)(A), the EPA notified the Governor of Ohio in a letter dated April 26, 2022, of an intended redesignation of a portion of the Canton, Ohio area as ''nonattainment'' for the 2008 Pb NAAQS. The EPA published a Notice of Availability (NOA) for this action in the **Federal Register** shortly thereafter, on May 3, 2022.[2]

Upon publication of the NOA in the **Federal Register**, a 30-day public comment period began. This comment period closed on June 2, 2022, and yielded three public comments, all of which proved supportive of the EPA's redesignation decision and intended nonattainment area boundary.

On August 22, 2022, Ohio EPA submitted their recommendations and response to the EPA's April 26, 2022, notification letter concurring with the EPA's boundaries for the intended nonattainment area in the Canton, Ohio area. Ohio EPA, in their response to the EPA's notification, acknowledged pending enforcement actions and a July 2, 2021, Consent Order for Preliminary Injunction in the Stark County Court of Common Pleas, which mandated that the Republic Steel facility, which is located within the bounds of the area to be redesignated, undertake certain actions to reduce Pb emissions. Since Ohio EPA's response concurred with the EPA's intended boundaries of the area to be redesignated, the EPA has not modified those boundaries and is finalizing its redesignation of the identified portion of the Canton area within Stark County, Ohio as ''nonattainment.''

The issuance of this final rule will require the state of Ohio to undertake certain planning requirements to reduce Pb concentrations within this newly redesignated nonattainment area, including, but not limited to, the requirement to submit within 18 months of redesignation, a revision to the Ohio state implementation plan (SIP) that provides for attainment of the 2008 Pb NAAQS as expeditiously as practicable, but no later than 5 years after the effective date of redesignation to nonattainment.

II. The 2008 Pb NAAQS

Under section 109 of the Act, the EPA has established primary and secondary NAAQS for certain pervasive air pollutants (referred to as ''criteria pollutants'') and conducts periodic reviews of the NAAQS to determine whether they should be revised or whether new NAAQS should be established. The primary NAAQS represent ambient air quality standards, the attainment and maintenance of which the EPA has determined, including a margin of safety, are requisite to protect the public health. The secondary NAAQS represent ambient air quality standards, the attainment and maintenance of which the EPA has determined are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.

Under the CAA, the EPA must establish NAAQS for criteria pollutants, including Pb. Lead is generally emitted in the form of particles that are deposited in water, soil, and dust. People may be exposed to Pb by inhaling it or by ingesting Pb-contaminated food, water, soil, or dust. Once in the body, Pb is quickly

[1] 75 FR 71033 (November 22, 2010); 76 FR 72097 (November 22, 2011).

[2] 87 FR 26147 (May 3, 2022).

absorbed into the bloodstream and can result in a broad range of adverse health effects including damage to the central nervous system, cardiovascular function, kidneys, immune system, and red blood cells. Children are particularly vulnerable to Pb exposure, in part because they are more likely to ingest Pb and in part because their still-developing bodies are more sensitive to the effects of Pb. The harmful effects to children's developing nervous systems (including their brains) arising from Pb exposure may include intelligence quotient (IQ)[3] loss, poor academic achievement, long-term learning disabilities, and an increased risk of delinquent behavior.[4]

The EPA first established primary and secondary Pb standards in 1978 at 1.5 micrograms per cubic meter (μg/m^3) as a quarterly average.[5] On October 15, 2008, the EPA revised the federal Pb standards to 0.15 μg/m^3 and revised the averaging time for the standards.[6] A violation of the 2008 Pb NAAQS occurs if any arithmetic 3-month mean concentration is greater than 0.15 μg/m^3.[7] Since the primary and secondary Pb standards are the same, we refer to them hereafter in this document using the singular Pb standard or NAAQS.

Following promulgation of any new or revised NAAQS, the EPA is required by CAA section 107(d) to designate areas throughout the nation as attaining or not attaining the NAAQS. The EPA initially designated all areas of the country as ''unclassifiable,'' ''unclassifiable/attainment,'' or ''nonattainment'' for the 2008 Pb NAAQS in two rounds on November 16, 2010, and November 8, 2011.

III. Clean Air Act Redesignation Authority

The CAA, under section 107(d)(3), provides the EPA with the authority to, at any time, notify the Governor of any state that available information indicates that the designation of any area or portion of an area should be revised. Such available information prompting a revised designation can include air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate. Once the EPA notifies a state, the state then has the opportunity to respond and submit supplemental information that the Governor considers appropriate. Before the EPA promulgates the redesignation, if any, the agency will consider the supplemental information provided by the state, making any modifications that the Administrator deems necessary. The EPA is not required under CAA section 107(d)(3) to seek public comment during the redesignations process, but we elected to do so for this area with respect to the 2008 Pb NAAQS to provide the public with an opportunity to give input for the EPA's consideration before promulgating any final redesignation.

IV. The EPA's Redesignation Decision and Supporting Air Quality Information

A. Applicable Regulatory Provisions

A determination of whether an area's air quality meets applicable standards is generally based upon the most recent 3 years of complete, quality-assured data recorded by established state and local air monitoring stations (SLAMS) and entered into the EPA's Air Quality System (AQS) database.[8] Data from ambient air monitors operated by state and local agencies in compliance with the EPA monitoring requirements must be submitted to AQS.[9] Monitoring agencies annually certify that these data are accurate to the best of their knowledge.[10] All data are reviewed to determine the area's air quality status for Pb in accordance with 40 CFR part 50, appendix R.

Under the EPA regulations in 40 CFR 50.16 and in accordance with 40 CFR part 50, appendix R, the 2008 Pb NAAQS is met when the design value is less than or equal to 0.15 μg/m^3 at each eligible monitoring site within the area. The Pb design value at each eligible monitoring site is the maximum valid rolling 3-month arithmetic mean Pb concentration from the 38-month period consisting of the most recent 3-year calendar period plus two previous months. The 3-month mean Pb concentrations are rounded to the nearest hundredth μg/m^3 for comparison to the NAAQS. Data completeness requirements for a given 3-month period are met if the average of the data capture rate of the three constituent monthly means is greater than or equal to 75 percent.[11]

B. Monitoring Network Considerations

Section 110(a)(2)(B)(i) of the CAA requires states to establish and operate air monitoring networks to compile data on ambient air quality for all criteria pollutants. The EPA's monitoring requirements are specified by regulations in 40 CFR part 58. These requirements are applicable to state and, where delegated, local air monitoring agencies that operate criteria pollutant monitors. The regulations in 40 CFR part 58 establish specific requirements for operating air quality surveillance networks to measure ambient concentrations of Pb, including requirements for measurement methods, network design, quality assurance procedures and, in the case of large urban areas, the minimum number of monitoring sites designated as SLAMS.

In sections 4.4 and 4.5 of appendix D to 40 CFR part 58, the EPA specifies minimum monitoring requirements for Pb, respectively, to operate at SLAMS. SLAMS produce data that are eligible for comparison with the NAAQS, and therefore, the monitor must be an approved federal reference method (FRM) monitor, federal equivalent method (FEM) monitor, or approved regional method (ARM) monitor.

The minimum number of required Pb SLAMS is described in section 4.5 of appendix D to 40 CFR part 58. There must be at least one source-oriented SLAMS site located to measure the maximum Pb concentration in ambient air resulting from each non-airport Pb source that emits 0.50 or more tons per year (tpy) and from each airport that emits 1.0 tpy or more based on either the most recent National Emission Inventory (NEI) or other scientifically justifiable methods and data.

According to the 2017 NEI, one non-airport source in Stark County, Ohio exceeded the 0.50 tpy threshold and therefore required source-oriented Pb monitoring: the Republic Steel plant located at 2633 Eighth Street NE in Canton, Ohio (Republic Steel).[12] Republic Steel is a steel manufacturer that manufactures leaded steel and other steel products.

[3] IQ is a score created by dividing a person's mental age score, obtained by administering an intelligence test, by the person's chronological age, both expressed in terms of years and months. ''Glossary of Important Assessment and Measurement Terms,'' Philadelphia, PA: National Council on Measurement in Education. 2016.

[4] Depending on the level of exposure, lead can adversely affect the nervous system, kidney function, immune system, reproductive and developmental systems and the cardiovascular system. For more information regarding the health effects of Pb exposure, see 73 FR 66964, November 12, 2008, or *http://www.epa.gov/airquality/lead/health.html.*

[5] 43 FR 46246 (October 5, 1978).

[6] 73 FR 66964 (November 12, 2008).

[7] 40 CFR 50.16.

[8] AQS is the EPA's repository of ambient air quality data.

[9] 40 CFR 58.16.

[10] 40 CFR 58.15.

[11] *See* 40 CFR part 50, appendix R, sections (1)c, 4(c), and 5(b).

[12] Ohio facility-level Pb emissions data from the 2017 NEI may be accessed on the EPA NEI website at *https://www.epa.gov/air-emissions-inventories/2017-national-emissions-inventory-nei-data.*

C. Canton, Ohio Ambient Air Monitoring Site

On June 6, 2017, an ambient air monitoring site was installed and began operating in Stark County to measure concentrations of Pb and other toxic metals. Ohio EPA, through its partnership with the Canton City Board of Health's Air Pollution Control Division,[13] installed this special purpose monitor (SPM) to meet the requirements of a state permit issued on December 12, 2016, to Republic Steel as part of operational changes made to its plant at 2633 Eighth Street NE in Canton, Ohio.[14]

In April 2019, Ohio EPA converted the designated primary Pb sampler at the Republic Steel ambient air monitoring site from a special purpose monitor to a SLAMS monitor. The conversion was made as a result of Ohio EPA's 2017 emissions inventory, which indicated that Republic Steel's Pb emissions were at 0.81 tpy, which exceeds the source-oriented 0.50 tpy monitoring threshold for non-airport sources in 40 CFR part 58, appendix D. The EPA requires SLAMS monitors to collect Pb samples at a minimum frequency of 1-in-6 days and those data be reported to the EPA's AQS.

On March 1, 2021, Ohio EPA began operating a second monitor at the Republic Steel ambient air monitoring site to collect additional Pb samples on a random day sampling schedule.[15] Pb data from both of these monitors are combined to calculate the monitoring site level design value for comparison to the NAAQS. Ohio EPA continued to also collect air samples to evaluate air quality specifically during leaded production at the Republic Steel plant. Because these air samplers were operated only during leaded production time periods, typically less than the routine 24-hour air samples required for air monitoring data used for NAAQS comparisons, the data are not reported to the EPA's AQS. Ohio EPA posts data from all Pb monitors on its website.[16]

The two ambient air quality monitors (Parameter Occurrence Code (POC) 1, POC 4) at the Republic Steel ambient air monitoring site measure ambient concentrations on a microscale level of 0 to 100 meters with a staggered schedule. POC 1 operates on the EPA sampling schedule of 1-in-6 days, and POC 4 operates on a randomized schedule. The POC is used to distinguish different instruments that measure the same parameter at the same monitoring site.

In April 2022, another ambient air quality monitoring site was installed at 719 Marietta Avenue NE, Canton, Ohio, and the Canton City Board of Health's Air Pollution Control Division began collecting data. The new ''Republic Community'' monitoring site (AQS Site No. 39–151–0025) operates two monitors, denoted as POC 1 and 4, on the same days and frequency as the Republic Steel monitoring site (AQS Site No. 39–151–0024). Data are reported to the EPA's AQS and are also available on Ohio EPA's website.[17]

D. Pb Data Considerations

In accordance with appendix R to 40 CFR part 50, compliance with the Pb NAAQS is determined based on data from 36 consecutive valid 3-month periods (*i.e.,* 38 months, or a 3-year calendar period and the preceding November and December). As detailed in 40 CFR part 50, appendix R section 4(c)(i), a 3-month mean Pb value is determined to be valid (*i.e.,* meets data completeness requirements) if the average of the data capture rate of the three constituent monthly means is greater than or equal to 75 percent.

Under 40 CFR 58.15, monitoring agencies must certify, on an annual basis, data collected at all SLAMS and at all FRM, FEM, and ARM special purpose monitor stations that meet the EPA quality assurance requirements. In doing so, monitoring agencies must certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of their knowledge. Ohio EPA annually certifies that the data it submits to AQS are quality-assured, including data collected by Ohio EPA at the Republic Steel monitoring site.

The EPA has evaluated the completeness of these data in accordance with the requirements of 40 CFR part 50, appendix R. The data collected by Ohio EPA at the Republic Steel ambient air monitoring site meet this completeness criterion for each 3-month period from 2019–2021.

Table 1 presents a summary of the latest available quality-assured Pb monitoring data from the Republic Steel ambient air monitoring site. A map showing the location of the monitor is included in the EPA's Technical Support Document (EPA TSD) accompanying this action, contained in the docket for this rulemaking and on the EPA's web page for Pb designations at *https://www.epa.gov/lead-designations.*

TABLE 1—AMBIENT AIR QUALITY MONITORING DATA AND Pb DESIGN VALUES FROM OHIO EPA'S REPUBLIC STEEL AMBIENT AIR MONITORING SITE [18]

Monitor	Maximum Pb 3-month rolling average (μg/m³) (number of complete months in parentheses)					Pb design value (μg/m³)		
	2017	2018	2019	2020	2021	2017–2019	2018–2020	2019–2021
AQS 39–151–0024: Republic Steel, 315 Georgetown Road NE, Canton, Ohio	0.11 (5)	0.20 (12)	0.21 (12)	0.13 (12)	0.40 (11)	0.21	0.21	0.40

The EPA considered the Pb NAAQS design value for the Republic Steel ambient air monitoring site in the Canton area in Stark County, Ohio by assessing the most recent 3 consecutive years (*i.e.,* 2019–2021) and 2 previous months of quality-assured, certified ambient air quality data in the EPA's AQS using data from FRM and/or FEM monitors that are sited and operated in accordance with 40 CFR parts 50 and 58. Data collected at the Republic Steel monitoring site indicate that the 2019–2021 design value representative of the Canton, Ohio area is 0.40μg/m³, which

[13] Canton City Board of Health, Air Pollution Control Division. *https://www.cantonhealth.org/apc/.*

[14] Ohio EPA Air Pollution Permit-to-Install (PTI), Permit Number: P0121793, Facility ID: 1576050694, Republic Steel. *http://wwwapp.epa.ohio.gov/dapc/permits_issued/1499790.pdf.*

[15] 2021–2022 Ohio EPA Air Monitoring Network Plan. *https://epa.ohio.gov/static/Portals27/ams/sites/2021-022_AMNP_Main_Report_Final.pdf.*

[16] Ohio EPA, Air Pollution Control, Reports & Data, Special Sampling Projects. *https://epa.ohio.gov/wps/portal/gov/epa/divisions-and-offices/air-pollution-control/reports-and-data/special-sampling-projects.*

[17] Ohio EPA Special Sampling Projects, Republic Steel, Canton, Stark County. *https://epa.ohio.gov/divisions-and-offices/air-pollution-control/reports-and-data/special-sampling-projects.*

[18] Information on the ambient air quality monitors and data used to calculate the Pb rolling averages and design values is publicly available at *https://www.epa.gov/aqs.*

is violating the 2008 Pb NAAQS of 0.15 μg/m^3.

E. Factors Considered in Determining Nonattainment Area Boundary

In initiating and promulgating this final redesignation, the EPA considered a number of factors. First, the ambient air quality monitoring data in the Canton, Ohio area show a violation well in excess of the 2008 Pb NAAQS based on data collected during 2019–2021, indicating that it is appropriate to revise the designation of the Canton area located within Stark County, Ohio to nonattainment.

Second, in determining the boundaries of the nonattainment area, the EPA relied on the same analytical process that it uses in the initial area designations process following promulgation of a new or revised NAAQS. Specifically, under CAA section 107(d)(1)(A)(i), the statutory authority for initial area designations, the EPA must designate as nonattainment any area that violates the NAAQS and any nearby area that contributes to ambient air quality in the violating area. The EPA issued guidance (2008 EPA Pb Guidance) associated with its initial designations under the 2008 Pb NAAQS that it applied in determining whether nearby areas were contributing to monitored violations.

Under the 2008 EPA Pb Guidance, the perimeter of a county containing the violating monitor is the initial presumptive boundary for a nonattainment area. To exclude any portion of the presumptive county boundary, the Guidance suggests that a demonstration is needed to show that violations are not occurring in the excluded portions of the county and that the excluded portions are not source areas that contribute to the observed violations. Moreover, the state and the EPA may also conduct additional area-specific analyses that could lead EPA to depart from the presumptive boundary to either include a larger area. The 2008 EPA Pb Guidance indicated the following eight factors are relevant to such an analysis: [19]

(1) Air quality in potentially included versus excluded areas;

(2) Emissions in areas potentially included versus excluded from the nonattainment area;

(3) Level of control of emission sources;

(4) Population density and degree of urbanization including commercial development in included versus excluded areas;

(5) Expected growth of the population (including extent, pattern, and rate of growth);

(6) Meteorology (weather/transport patterns);

(7) Geography/topography (mountain ranges or other air basin boundaries); and

(8) Jurisdictional boundaries (*e.g.,* counties, air districts, reservations, etc.).

In addition to an analysis of the eight factors above, states can choose to recommend Pb nonattainment boundaries by using one, or a combination of the following techniques:

- Qualitative analysis;
- Spatial interpolation of air quality monitoring data; or
- Air quality simulation by dispersion modeling.[20]

For purposes of this redesignation, all eight factors listed in the 2008 Guidance were evaluated, but the EPA concluded that population growth, geography, and topography did not play a significant factor in determining the nonattainment area boundary in Stark County, Ohio. The EPA's detailed evaluation of the violating monitoring site, contributing sources, and final area boundaries based on the weight of evidence of the previously identified factors is included in the TSD, which is located in the docket for this redesignation action. The EPA's final boundaries of the redesignated area encompass the portions of Stark County that are bounded on the north by State Route OH–153 (12th Street NE; Mahoning Road), on the east by Broadway Avenue, on the south by State Route OH–172 (Tuscarawas Street E; Lincoln Street E), and the west by State Route OH–43—Northbound (Cherry Avenue NE). A map showing the boundaries of our final nonattainment area for Canton, Ohio is included in the final TSD for this action.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action is a redesignation of one area to nonattainment and does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to the CAA, which does not require notice and comment rulemaking to take this action.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The division of responsibility between the federal government and the states for purposes of implementing the NAAQS is established under the CAA.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications. It will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. However, we note that the protection offered by the Pb NAAQS may be especially important for children because neurological effects in children are among, if not the most, sensitive health endpoints for Pb exposure. Because children are considered a sensitive population, in setting the Pb NAAQS we carefully evaluated the environmental health effects of exposure to Pb pollution among children. These effects and the

[19] 73 FR 67033 (November 12, 2008).

[20] 73 FR 67033 (November 12, 2008).

size of the population affected are summarized in the EPA's 2006 Air Quality Criteria Document for Pb and in the proposed and final Pb NAAQS rules. (*http://www.epa.gov/airquality/lead/fr/20081112.pdf*)

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action, on which the EPA offered public notice and comment, changes the air quality designation of an area and triggers an obligation on the part of the State to develop an implementation plan to improve air quality in the area so that it meets the Pb NAAQS. A forthcoming implementation plan by the State will also be available for public notice and comment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the U.S. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. 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 May 9, 2023. 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* CAA section 307(b)(2).

VI. Statutory Authority

The statutory authority for this action is provided by 42 U.S.C. 7401, *et seq.*

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Lead.

Michael S. Regan,
Administrator.

For the reasons set forth in the preamble, 40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

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

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

Subpart C—Section 107 Attainment Status Designations

■ 2. In § 81.336, the table entitled ''Ohio—2008 Lead NAAQS'' is amended by adding an entry for ''Canton—Stark County, OH:'' before the entry ''Cleveland, OH:'' to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—2008 LEAD NAAQS

Designated area	Designation for the 2008 NAAQS [a]	
	Date [1]	Type
* * * * *	*	*
Canton—Stark County, OH:	April 10, 2023	Nonattainment.
Stark County (part).		
Nonattainment area is bounded by the following roadways:		
North: State Route OH–153 (12th Street NE; Mahoning Road).		
East: Broadway Avenue.		
South: State Route OH–172 (Tuscarawas Street E; Lincoln Street E).		
West: State Route OH–43—Northbound (Cherry Avenue NE).		
* * * * *	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] December 31, 2011, unless otherwise noted.

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BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230306–0065; RTID 0648–XC365]

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands; Final 2023 and 2024 Harvest Specifications for Groundfish

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

ACTION: Final rule; harvest specifications and closures.

SUMMARY: NMFS announces final 2023 and 2024 harvest specifications, apportionments, and prohibited species catch allowances for the groundfish fishery of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to establish harvest limits for groundfish during the remainder of the 2023 and the start of the 2024 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The 2023 harvest specifications supersede those previously set in the final 2022 and 2023 harvest specifications, and the 2024 harvest specifications will be superseded in early 2024 when the final 2024 and 2025 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the Bering Sea and Aleutian Islands Management Area (BSAI) in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; MSA).

DATES: Harvest specifications and closures are effective from 1200 hours, Alaska local time (A.l.t.), March 10, 2023, through 2400 hours, A.l.t., December 31, 2024.

ADDRESSES: Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (EIS), Record of Decision (ROD), and the annual Supplementary Information Reports (SIRs) to the Final EIS prepared for this action are available from *https://www.fisheries.noaa.gov/region/alaska.* The 2022 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the BSAI, dated November 2022, as well as the SAFE reports for previous years, are available from the North Pacific Fishery Management Council (Council) at 1007 West Third Ave., Suite 400, Anchorage, AK 99501, phone 907–271–2809, or from the Council's website at *https://www.npfmc.org/.*

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR part 679 implement the FMP and govern the groundfish fisheries in the BSAI. The Council prepared the FMP, and NMFS approved it, under the Magnuson-Stevens Act. General regulations governing U.S. fisheries also appear at 50 CFR part 600.

The FMP and its implementing regulations require NMFS, after consultation with the Council, to specify annually the total allowable catch (TAC) for each target species category. The sum of all TACs for all groundfish species in the BSAI must be within the optimum yield (OY) range of 1.4 million to 2.0 million metric tons (mt) (see § 679.20(a)(1)(i)(A) and 679.20(a)(2)). This final rule specifies the sum of the TAC at 2.0 million mt for 2023 and 2.0 million mt for 2024. NMFS also must specify apportionments of TAC; prohibited species catch (PSC) allowances and prohibited species quota (PSQ) reserves established by § 679.21; seasonal allowances of pollock, Pacific cod, and Atka mackerel TAC; American Fisheries Act allocations; Amendment 80 allocations; Community Development Quota (CDQ) reserve amounts established by § 679.20(b)(1)(ii); acceptable biological catch (ABC) surpluses and reserves for CDQ groups and any Amendment 80 cooperatives for flathead sole, rock sole, and yellowfin sole; and halibut discard mortality rates (DMRs). The final harvest specifications set forth in Tables 1 through 22 of this action satisfy these requirements.

Section 679.20(c)(3)(i) further requires that NMFS consider public comment on the proposed harvest specifications and, after consultation with the Council, publish final harvest specifications in the **Federal Register**. The proposed 2023 and 2024 harvest specifications for the groundfish fishery of the BSAI were published in the **Federal Register** on December 14, 2022 (87 FR 76435). Comments were invited and accepted through January 13, 2023. As discussed in the Response to Comments section below, NMFS received six letters raising seventeen distinct comments during the public comment period for the proposed BSAI groundfish harvest specifications. NMFS's responses are addressed in the Response to Comments section below.

NMFS consulted with the Council on the final 2023 and 2024 harvest specifications during the December 2022 Council meeting. After considering public comments during public meetings and public comments submitted for the proposed rule (87 FR 76435), as well as biological and socioeconomic data that were available at the Council's December 2022 meeting, NMFS implements in this final rule the final 2023 and 2024 harvest specifications as recommended by the Council.

ABC and TAC Harvest Specifications

The final ABC amounts for Alaska groundfish are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods used to calculate stock biomass. In general, the development of ABCs and overfishing levels (OFLs) involves sophisticated statistical analyses of fish populations. The FMP specifies a series of six tiers to define OFL and ABC amounts based on the level of reliable information available to fishery scientists. Tier 1 represents the highest level of information quality available, while Tier 6 represents the lowest.

In December 2022, the Council, its Scientific and Statistical Committee (SSC), and its Advisory Panel (AP) reviewed current biological and harvest information about the condition of the BSAI groundfish stocks. The Council's BSAI Groundfish Plan Team (Plan Team) compiled and presented this information in the 2022 SAFE report for the BSAI groundfish fisheries, dated November 2022 (see **ADDRESSES**). The SAFE report contains a review of the latest scientific analyses and estimates of each species' biomass and other biological parameters, as well as summaries of the available information on the BSAI ecosystem and the economic condition of groundfish fisheries off Alaska. NMFS notified the public of the comment period for these harvest specifications—and of the publication of the 2022 SAFE report—in the proposed harvest specifications (87 FR 76435, December 14, 2022). From the data and analyses in the SAFE report, the Plan Team recommended an OFL and ABC for each species and species group at the November 2022 Plan Team meeting.

In December 2022, the SSC, AP, and Council reviewed the Plan Team's recommendations. The final TAC recommendations were based on the ABCs, and were adjusted for other biological and socioeconomic

considerations, including maintaining the sum of all the TACs within the required OY range of 1.4 million to 2.0 million mt. As required by annual catch limit rules for all fisheries (74 FR 3178, January 16, 2009), none of the Council's recommended 2023 or 2024 TACs exceed the final 2023 or 2024 ABCs for any species or species group. NMFS finds that the Council's recommended OFLs, ABCs, and TACs are consistent with the preferred harvest strategy outlined in the FMP and the biological condition of groundfish stocks as described in the 2022 SAFE report that was approved by the Council. Therefore, this final rule provides notification that the Secretary of Commerce approves the final 2023 and 2024 harvest specifications as recommended by the Council.

The 2023 harvest specifications set in this final action supersede the 2023 harvest specifications previously set in the final 2022 and 2023 harvest specifications (87 FR 11626, March 2, 2022). The 2024 harvest specifications herein will be superseded in early 2024 when the final 2024 and 2025 harvest specifications are published. Pursuant to this final action, the 2023 harvest specifications therefore will apply for the remainder of the current year (2023), while the 2024 harvest specifications are projected only for the following year (2024) and will be superseded in early 2024 by the final 2024 and 2025 harvest specifications. Because this final action (published in early 2023) will be superseded in early 2024 by the publication of the final 2024 and 2025 harvest specifications, it is projected that this final action will implement the harvest specifications for the BSAI for approximately 1 year.

Other Actions Affecting the 2023 and 2024 Harvest Specifications

State of Alaska Guideline Harvest Levels

For 2023 and 2024, the Board of Fisheries (BOF) for the State of Alaska (State) established the guideline harvest level (GHL) for vessels using pot, longline, jig, and hand troll gear in State waters in the State's Aleutian Islands (AI) State waters sablefish registration area that includes all State waters west of Scotch Cap Light (164°44.72′ W longitude) and south of Cape Sarichef (54°36′ N latitude). The 2023 AI GHL is set at 5 percent (865 mt) of the combined 2023 Bering Sea subarea (BS) and AI subarea ABC (mt). The 2024 AI GHL is set at 5 percent (1,025 mt) of the combined 2024 BS subarea and AI subarea ABC (mt). The State's AI sablefish registration area includes areas adjacent to parts of the Federal BS. The Council and its BSAI Groundfish Plan Team (Plan Team), SSC, and AP recommended that the sum of all State and Federal waters sablefish removals from the BS and AI not exceed the ABC recommendations for sablefish in the BS and AI. Accordingly, the Council recommended, and NMFS approves, that the 2023 and 2024 sablefish TACs in the BS and AI account for the State's GHLs for sablefish caught in State waters.

For 2023 and 2024, the BOF for the State established the GHL for vessels using pot gear in State waters in the BS equal to 12 percent of the Pacific cod ABC in the BS when the ABC is between 125,000 mt and 150,000 mt. For 2023, the BS Pacific cod ABC is 144,834 mt, and for 2024, it is 140,159 mt. Therefore, the GHL in the BS for pot gear will be 12 percent for 2023 (17,380 mt) and 2024 (16,819 mt). Also, for 2023 and 2024, the BOF established an additional GHL for vessels using jig gear in State waters in the BS equal to 45 mt of Pacific cod in the BS. The Council and its Plan Team, SSC, and AP recommended that the sum of all State and Federal waters Pacific cod removals from the BS not exceed the ABC recommendations for Pacific cod in the BS. Accordingly, the Council recommended, and NMFS approves, that the 2023 and 2024 Pacific cod TACs in the BS account for the State's GHLs for Pacific cod caught in State waters in the BS.

For 2023 and 2024, the BOF for the State established the GHL in State waters in the Aleutian Islands subarea (AI) equal to 39 percent of the AI ABC. The AI GHL will increase annually by 4 percent of the AI ABC, if 90 percent of the GHL is harvested by November 15 of the preceding year, but may not exceed 39 percent of the AI ABC or 15 million pounds (6,804 mt). For 2023 and for 2024, 39 percent of the AI ABC is 5,387 mt. The Council and its Plan Team, SSC, and AP recommended that the sum of all State and Federal waters Pacific cod removals from the AI not exceed the ABC recommendations for Pacific cod in the AI. Accordingly, the Council recommended, and NMFS approves, that the 2023 and 2024 Pacific cod TACs in the AI account for the State's GHL of 5,387 mt for Pacific cod caught in State waters in the AI.

Halibut Abundance-Based Management for the Amendment 80 Program PSC Limit

On December 9, 2022, NMFS published a proposed rule (87 FR 75570), and an extension of public comment (87 FR 75569), to implement Amendment 123 to the FMP, which if approved would establish abundance-based management of Amendment 80 Program PSC for Pacific halibut. The proposed action would replace the current Amendment 80 sector static halibut PSC limit (1,745 mt) with a process for annually setting the Amendment 80 sector halibut PSC limit based on the most recent halibut abundance estimates from the International Pacific Halibut Commission setline survey and the NMFS Alaska Fisheries Science Center Eastern Bering Sea shelf trawl survey. The annual process would use a table with pre-established halibut abundance ranges based on those surveys. The annual Amendment 80 sector halibut PSC limit would be set at the value found at the intercept of the results from the most recent surveys. Further details are available in the proposed rule to implement Amendment 123. If the FMP amendment and its implementing regulations are approved by the Secretary of Commerce, the action is anticipated to be effective in 2024. Until effective, NMFS will continue to use the current Amendment 80 halibut PSC limit listed at § 679.21(b)(1) and published in the harvest specifications.

Pacific Cod Trawl Cooperative Limited Access Privilege Program

On February 9, 2023, NMFS published a proposed rule to implement Amendment 122 to the FMP, which if approved would implement a limited access privilege program called the Pacific cod Trawl Cooperative (PCTC) Program (88 FR 8592, February 9, 2023). The PCTC Program would allocate quota share (QS) to groundfish License Limitation Program license holders and to processors based on history during the qualifying years. Under this program, QS holders would be required to join cooperatives annually. Cooperatives would be allocated the BSAI trawl catcher vessel (CV) sector's A and B season Pacific cod allocations as an exclusive harvest privilege in the form of cooperative quota, equivalent to the aggregate QS of all cooperative members. NMFS anticipates that the regulations at § 679.20(a)(7)(viii) will be removed through implementation of the PCTC Program, if approved. Further details are available in the proposed rule to implement Amendment 122. If the FMP amendment and its implementing regulations are approved by the Secretary of Commerce, the action is anticipated to be effective in 2024. Until effective, NMFS will continue the current management of the BSAI trawl CV Pacific cod allocation.

Amendment 124 to the BSAI FMP for Groundfish To Revise Individual Fishing Quota (IFQ) Program Regulations

On November 23, 2022, NMFS published a proposed rule (87 FR 71559) to implement Amendment 124 to the FMP, which if approved would allow jig gear as an authorized fishing gear type in the BSAI sablefish IFQ and CDQ fisheries. The Council's intent in recommending Amendment 124 is to increase entry-level opportunities and increase flexibility for IFQ holders. This is because jig gear is a smaller investment than other gear types and does not require significant vessel retrofits as with other gear. Additionally, jig gear is already an authorized gear type for the harvest of halibut IFQ and CDQ and this action would further align the authorized gear types in the halibut and sablefish IFQ and CDQ fisheries. Further details are available in the proposed rule to implement Amendment 124. If the FMP amendment and its implementing regulations are approved by the Secretary of Commerce, the action is anticipated to be effective for the 2023 IFQ and CDQ season.

Changes From the Proposed 2023 and 2024 Harvest Specifications for the BSAI

The Council's recommendations for the proposed 2023 and 2024 harvest specifications (87 FR 76435, December 14, 2022) were based largely on information contained in the 2021 SAFE report for the BSAI groundfish fisheries. Through the proposed harvest specifications, NMFS notified the public that these harvest specifications could change, as the Council would consider information contained in the 2022 SAFE report; recommendations from the Plan Team, SSC, and AP; and public comments when making its recommendations for final harvest specifications at the December 2022 Council meeting. NMFS further notified the public that, as required by the FMP and its implementing regulations, the sum of the TACs must be within the OY range of 1.4 million and 2.0 million mt.

Information contained in the 2022 SAFE report indicates biomass changes from the 2021 SAFE report for several groundfish species. The 2022 SAFE report was made available for public review during the public comment period for the proposed harvest specifications. At the December 2022 Council meeting, the SSC recommended the 2023 and 2024 OFLs and ABCs based on the best and most recent information contained in the 2022 SAFE report. The SSC's recommendation resulted in an ABC sum total for all BSAI groundfish species in excess of 2.0 million mt for both 2023 and 2024.

Based on larger spawning biomass estimates, the Council recommends final BS pollock TACs increase by 11,000 mt in 2023 and 13,000 mt in 2024 compared to the proposed 2023 and 2024 BS pollock TACs. The Council also recommends increasing the BSAI rock sole TAC by 11,000 mt in 2023 and 11,000 mt in 2024, and increasing the flathead sole TAC by 10,000 mt in 2023 and 10,000 mt in 2024, compared to the proposed 2023 and 2024 TACs. In terms of tonnage, the Council recommends reducing the TACs from the proposed TACs of several species of lower economic value to maintain an overall total TAC within the required OY range of 1.4 to 2.0 million mt with Alaska plaice, arrowtooth flounder, northern rockfish, and ''other flatfish'' having the largest TAC decreases. In terms of percentage, the largest TAC decreases from the proposed TACs of lower economically valued species were for Alaska plaice, arrowtooth flounder, Greenland turbot, Kamchatka flounder, octopuses, ''other flatfish,'' northern rockfish, and sharks. The Council recommends lowering the TACs of both BS and AI Pacific cod in 2023 and 2024 due to lower spawning biomasses.

The changes to TACs between the proposed and final harvest specifications are based on the most recent scientific and socioeconomic information and are consistent with the FMP, regulatory obligations, and harvest strategy as described in the proposed and final harvest specifications, including the required OY range of 1.4 million to 2.0 million mt. These changes are compared in Table 1A.

Table 1 lists the Council's recommended final 2023 OFL, ABC, TAC, initial TAC (ITAC), CDQ reserve allocations, and non-specified reserves of the BSAI groundfish species and species groups; and Table 2 lists the Council's recommended final 2024 OFL, ABC, TAC, ITAC, CDQ reserve allocations, and non-specified reserves of the BSAI groundfish species and species groups. NMFS concurs in these recommendations. These final 2023 and 2024 TAC amounts for the BSAI are within the OY range established for the BSAI and do not exceed the ABC for any species or species group. The apportionment of TAC amounts among fisheries and seasons is discussed below.

TABLE 1—FINAL 2023 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NON-SPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]

[Amounts are in metric tons]

Species	Area	2023					
		OFL	ABC	TAC	ITAC [2]	CDQ [3]	Nonspecified reserves
Pollock [4]	BS	3,381,000	1,910,000	1,300,000	1,170,000	130,000	
	AI	52,383	43,413	19,000	17,100	1,900	
	Bogoslof	115,146	86,360	300	300		
Pacific cod [5]	BS	172,495	144,834	127,409	113,776	13,633	
	AI	18,416	13,812	8,425	7,524	901	
Sablefish [6]	Alaska-wide	47,390	40,502	n/a	n/a	n/a	
	BS	n/a	8,417	7,996	6,597	1,099	300
	AI	n/a	8,884	8,440	6,858	1,424	158
Yellowfin sole	BSAI	404,882	378,499	230,000	205,390	24,610	
Greenland turbot	BSAI	4,645	3,960	3,960	3,366	n/a	
	BS	n/a	3,338	3,338	2,837	357	144
	AI	n/a	622	622	529		93
Arrowtooth flounder	BSAI	98,787	83,852	15,000	12,750	1,605	645
Kamchatka flounder	BSAI	8,946	7,579	7,579	6,442		1,137
Rock sole [7]	BSAI	166,034	121,719	66,000	58,938	7,062	
Flathead sole [8]	BSAI	79,256	65,344	35,500	31,702	3,799	
Alaska plaice	BSAI	40,823	33,946	17,500	14,875		2,625
Other flatfish [9]	BSAI	22,919	17,189	4,500	3,825		675
Pacific ocean perch	BSAI	50,133	42,038	37,703	33,157	n/a	
	BS	n/a	11,903	11,903	10,118		1,785

TABLE 1—FINAL 2023 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NON-SPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]—Continued

[Amounts are in metric tons]

Species	Area	2023					
		OFL	ABC	TAC	ITAC [2]	CDQ [3]	Nonspecified reserves
	EAI	n/a	8,152	8,152	7,280	872	
	CAI	n/a	5,648	5,648	5,044	604	
	WAI	n/a	16,335	12,000	10,716	1,284	
Northern rockfish	BSAI	22,776	18,687	11,000	9,350		1,650
Blackspotted/Rougheye rockfish [10]	BSAI	703	525	525	446		79
BS/EAI	n/a	359	359	305			54
	CAI/WAI	n/a	166	166	141		25
Shortraker rockfish	BSAI	706	530	530	451		80
Other rockfish [11]	BSAI	1,680	1,260	1,260	1,071		189
	BS	n/a	880	880	748		132
	AI	n/a	380	380	323		57
Atka mackerel	BSAI	118,787	98,588	69,282	61,869	7,413	
	BS/EAI	n/a	43,281	27,260	24,343	2,917	
	CAI	n/a	17,351	17,351	15,494	1,857	
	WAI	n/a	37,956	24,671	22,031	2,640	
Skates	BSAI	46,220	38,605	27,441	23,325		4,116
Sharks	BSAI	689	450	250	213		38
Octopuses	BSAI	4,769	3,576	400	340		60
Total		4,859,585	3,155,268	2,000,000	1,789,662	196,564	13,773

Note: Regulatory areas and districts are defined at § 679.2 (BSAI=Bering Sea and Aleutian Islands management area, BS=Bering Sea subarea, AI=Aleutian Islands subarea, EAI=Eastern Aleutian district, CAI=Central Aleutian district, WAI=Western Aleutian district).

[1] These amounts apply to the entire BSAI management area unless otherwise specified. With the exception of pollock, and for the purpose of these harvest specifications, the Bering Sea subarea (BS) includes the Bogoslof District.

[2] Except for pollock, the portion of the sablefish TAC allocated to fixed gear, and Amendment 80 species (Atka mackerel, yellowfin sole, rock sole, flathead sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 15 percent of each TAC is placed into a non-specified reserve (§ 679.20(b)(1)(i)). The ITAC for these species is the remainder of the TAC after the subtraction of these reserves. For pollock and Amendment 80 species, ITAC is the non-CDQ allocation of TAC (see footnotes 3 and 4).

[3] For the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 10.7 percent of the TAC is reserved for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C)). 20 percent of the sablefish TAC allocated to fixed gear, 7.5 percent of the sablefish TAC allocated to trawl gear, and 10.7 percent of the TACs for Bering Sea Greenland turbot and arrowtooth flounder are reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(B) and (D)). Aleutian Islands Greenland turbot, ''other flatfish,'' Alaska plaice, Bering Sea Pacific ocean perch, Kamchatka flounder, northern rockfish, shortraker rockfish, blackspotted/rougheye rockfish, ''other rockfish,'' skates, sharks, and octopuses are not allocated to the CDQ program.

[4] Under § 679.20(a)(5)(i)(A), the annual BS pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (50,000 mt), is further allocated by sector for a pollock directed fishery as follows: inshore—50 percent; catcher/processor—40 percent; and motherships—10 percent. Under § 679.20(a)(5)(iii)(B)(*2*), the annual AI pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (2,500 mt), is allocated to the Aleut Corporation for a pollock directed fishery.

[5] The BS Pacific cod TAC is set to account for the 12 percent, plus 45 mt, of the BS ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS. The AI Pacific cod TAC is set to account for 39 percent of the AI ABC for the State guideline harvest level in State waters of the AI.

[6] The sablefish OFL and ABC are Alaska-wide and include the Gulf of Alaska. The Alaska-wide sablefish OFL and ABC are included in the total OFL and ABC. The BS and AI sablefish TACs are set to account for the 5 percent of the BS and AI ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS and AI.

[7] ''Rock sole'' includes *Lepidopsetta polyxystra* (Northern rock sole) and *Lepidopsetta bilineata* (Southern rock sole).

[8] ''Flathead sole'' includes *Hippoglossoides elassodon* (flathead sole) and *Hippoglossoides robustus* (Bering flounder).

[9] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.

[10] ''Blackspotted/Rougheye rockfish'' includes *Sebastes melanostictus* (blackspotted) and *Sebastes aleutianus* (rougheye).

[11] ''Other rockfish'' includes all *Sebastes* and *Sebastolobus* species except for dark rockfish, Pacific ocean perch, northern rockfish, blackspotted/rougheye rockfish, and shortraker rockfish.

TABLE 1a—COMPARISON OF FINAL 2023 AND 2024 WITH PROPOSED 2023 AND 2024 TOTAL ALLOWABLE CATCH IN THE BSAI

[Amounts are in metric tons]

Species	Area [1]	2023 final TAC	2023 and 2024 proposed TAC	2023 difference from proposed	2023 percentage difference from proposed	2024 final TAC	2024 difference from proposed	2024 percentage difference from proposed
Pollock	BS	1,300,000	1,289,000	11,000	0.9	1,302,000	13,000	1.0
	AI	19,000	19,000			19,000		
	Bogoslof	300	250	50	20.0	300	50	20.0
Pacific cod	BS	127,409	133,459	(6,050)	(4.5)	123,295	(10,164)	(7.6)
	AI	8,425	13,796	(5,371)	(38.9)	8,425	(5,371)	(38.9)
Sablefish	BS	7,996	6,529	1,467	22.5	9,676	3,147	48.2
	AI	8,440	7,786	654	8.4	9,793	2,007	25.8
Yellowfin sole	BSAI	230,000	230,000			230,656	656	0.3
Greenland turbot	BS	3,338	4,825	(1,487)	(30.8)	2,836	(1,989)	(41.2)
	AI	622	899	(277)	(30.8)	528	(371)	(41.3)
Arrowtooth flounder	BSAI	15,000	20,000	(5,000)	(25.0)	15,000	(5,000)	(25.0)
Kamchatka flounder	BSAI	7,579	9,393	(1,814)	(19.3)	7,435	(1,958)	(20.8)
Rock sole	BSAI	66,000	55,000	11,000	20.0	66,000	11,000	20.0
Flathead sole	BSAI	35,500	25,500	10,000	39.2	35,500	10,000	39.2
Alaska plaice	BSAI	17,500	29,082	(11,582)	(39.8)	18,000	(11,082)	(38.1)
Other flatfish	BSAI	4,500	10,000	(5,500)	(55.0)	4,500	(5,500)	(55.0)
Pacific ocean perch	BS	11,903	9,956	1,947	19.6	11,700	1,744	17.5

TABLE 1a—COMPARISON OF FINAL 2023 AND 2024 WITH PROPOSED 2023 AND 2024 TOTAL ALLOWABLE CATCH IN THE BSAI—Continued

[Amounts are in metric tons]

Species	Area [1]	2023 final TAC	2023 and 2024 proposed TAC	2023 difference from proposed	2023 percentage difference from proposed	2024 final TAC	2024 difference from proposed	2024 percentage difference from proposed
	EAI	8,152	7,774	378	4.9	8,013	239	3.1
	CAI	5,648	5,722	(74)	(1.3)	5,551	(171)	(3.0)
	WAI	12,000	10,500	1,500	14.3	13,000	2,500	23.8
Northern rockfish	BSAI	11,000	17,000	(6,000)	(35.3)	11,000	(6,000)	(35.3)
Blackspotted and Rougheye rockfish	BS/EAI	359	334	25	7.5	388	54	16.2
	CAI/WAI	166	183	(17)	(9.3)	182	(1)	(0.5)
Shortraker rockfish	BSAI	530	541	(11)	(2.0)	530	(11)	(2.0)
Other rockfish	BS	880	919	(39)	(4.2)	880	(39)	(4.2)
	AI	380	394	(14)	(3.6)	380	(14)	(3.6)
Atka mackerel	EAI/BS	27,260	25,000	2,260	9.0	30,000	5,000	20.0
	CAI	17,351	15,470	1,881	12.2	15,218	(252)	(1.6)
	WAI	24,671	20,488	4,183	20.4	21,637	1,149	5.6
Skates	BSAI	27,441	30,000	(2,559)	(8.5)	27,927	(2,073)	(6.9)
Sharks	BSAI	250	500	(250)	(50.0)	250	(250)	(50.0)
Octopuses	BSAI	400	700	(300)	(42.9)	400	(300)	(42.9)
Total	BSAI	2,000,000	2,000,000			2,000,000		

[1] Bering Sea subarea (BS), Aleutian Islands subarea (AI), Bering Sea and Aleutian Islands management area (BSAI), Eastern Aleutian District (EAI), Central Aleutian District (CAI), and Western Aleutian District (WAI).

TABLE 2—FINAL 2024 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NON-SPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]

[Amounts are in metric tons]

Species	Area	2024					
		OFL	ABC	TAC	ITAC [2]	CDQ [3]	Nonspecified reserves
Pollock [4]	BS	4,639,000	2,275,000	1,302,000	1,171,800	130,200	
	AI	52,043	43,092	19,000	17,100	1,900	
	Bogoslof	115,146	86,360	300	300		
Pacific cod [5]	BS	166,814	140,159	123,295	110,102	13,193	
	AI	18,416	13,812	8,425	7,524	901	
Sablefish [6]	Alaska-wide	48,561	41,539	n/a	n/a	n/a	
	BS	n/a	10,185	9,676	4,112	363	363
	AI	n/a	10,308	9,793	2,081	184	184
Yellowfin sole	BSAI	495,155	462,890	230,656	205,976	24,680	
Greenland turbot	BSAI	3,947	3,364	3,364	2,859	n/a	
	BS	n/a	2,836	2,836	2,411	303	122
	AI	n/a	528	528	449		79
Arrowtooth flounder	BSAI	103,070	87,511	15,000	12,750	1,605	645
Kamchatka flounder.	BSAI	8,776	7,435	7,435	6,320		1,115
Rock sole [7]	BSAI	196,011	119,969	66,000	58,938	7,062	
Flathead sole [8]	BSAI	81,167	66,927	35,500	31,702	3,799	
Alaska plaice	BSAI	43,328	36,021	18,000	15,300		2,700
Other flatfish [9]	BSAI	22,919	17,189	4,500	3,825		675
Pacific ocean perch.	BSAI	49,279	41,322	38,264	33,667	n/a	
	BS	n/a	11,700	11,700	9,945		1,755
	EAI	n/a	8,013	8,013	7,156	857	
	CAI	n/a	5,551	5,551	4,957	594	
	WAI	n/a	16,058	13,000	11,609	1,391	
Northern rockfish	BSAI	22,105	18,135	11,000	9,350		1,650
Blackspotted/ Rougheye rockfish [10]	BSAI	763	570	570	485	86	58
	BS/EAI	n/a	388	388	330		
	CAI/WAI	n/a	182	182	155		27
Shortraker rockfish	BSAI	706	530	530	451		80
Other rockfish [11]	BSAI	1,680	1,260	1,260	1,071		189
	BS	n/a	880	880	748		132
	AI	n/a	380	380	323		57
Atka mackerel	BSAI	101,188	86,464	66,855	59,702	7,153	
	EAI/BS	n/a	37,958	30,000	26,790	3,210	
	CAI	n/a	15,218	15,218	13,590	1,628	
	WAI	n/a	33,288	21,637	19,322	2,315	
Skates	BSAI	44,168	36,837	27,927	23,738		4,189
Sharks	BSAI	689	450	250	213		38

TABLE 2—FINAL 2024 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NON-SPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]—Continued

[Amounts are in metric tons]

Species	Area	2024					
		OFL	ABC	TAC	ITAC [2]	CDQ [3]	Nonspecified reserves
Octopuses	BSAI	4,769	3,576	400	340		60
Total		6,219,700	3,590,412	2,000,000	1,779,703	194,185	13,928

Note: Regulatory areas and districts are defined at § 679.2 (BSAI=Bering Sea and Aleutian Islands management area, BS=Bering Sea subarea, AI=Aleutian Islands subarea, EAI=Eastern Aleutian district, CAI=Central Aleutian district, WAI=Western Aleutian district).

[1] These amounts apply to the entire BSAI management area unless otherwise specified. With the exception of pollock, and for the purpose of these harvest specifications, the Bering Sea subarea (BS) includes the Bogoslof District.

[2] Except for pollock, the portion of the sablefish TAC allocated to fixed gear, and Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 15 percent of each TAC is put into a non-specified reserve (§ 679.20(b)(1)(i)). The ITAC for these species is the remainder of the TAC after the subtraction of these reserves. For pollock and Amendment 80 species, ITAC is the non-CDQ allocation of TAC (see footnotes 3 and 4).

[3] For the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 10.7 percent of the TAC is reserved for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C)). 20 percent of the sablefish TAC allocated to fixed gear, 7.5 percent of the sablefish TAC allocated to trawl gear, and 10.7 percent of the TACs for Bering Sea Greenland turbot and arrowtooth flounder are reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(B) and (D)). The 2024 fixed gear portion of the sablefish ITAC and CDQ reserve will not be specified until the final 2024 and 2025 harvest specifications. Aleutian Islands Greenland turbot, ''other flatfish,'' Alaska plaice, Bering Sea Pacific ocean perch, Kamchatka flounder, northern rockfish, shortraker rockfish, blackspotted/rougheye rockfish, ''other rockfish,'' skates, sharks, and octopuses are not allocated to the CDQ program.

[4] Under § 679.20(a)(5)(i)(A), the annual BS pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (50,000 mt), is further allocated by sector for a pollock directed fishery as follows: inshore—50 percent; catcher/processor—40 percent; and motherships—10 percent. Under § 679.20(a)(5)(iii)(B)(*2*), the annual AI pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (2,500 mt), is allocated to the Aleut Corporation for a pollock directed fishery.

[5] The BS Pacific cod TAC is set to account for the 12 percent, plus 45 mt, of the BS ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS. The AI Pacific cod TAC is set to account for 39 percent of the AI ABC for the State guideline harvest level in State waters of the AI.

[6] The sablefish OFL and ABC are Alaska-wide and include the Gulf of Alaska. The Alaska-wide sablefish OFL and ABC are included in the total OFL and ABC. The BS and AI sablefish TACs are set to account for the 5 percent of the BS and AI ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS and AI.

[7] ''Rock sole'' includes *Lepidopsetta polyxystra* (Northern rock sole) and *Lepidopsetta bilineata* (Southern rock sole).

[8] ''Flathead sole'' includes *Hippoglossoides elassodon* (flathead sole) and *Hippoglossoides robustus* (Bering flounder).

[9] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.

[10] ''Blackspotted/Rougheye rockfish'' includes *Sebastes melanostictus* (blackspotted) and *Sebastes aleutianus* (rougheye).

[11] ''Other rockfish'' includes all *Sebastes* and *Sebastolobus* species except for dark rockfish, Pacific ocean perch, northern rockfish, blackspotted/rougheye rockfish, and shortraker rockfish.

Groundfish Reserves and the Incidental Catch Allowance (ICA) for Pollock, Atka Mackerel, Flathead Sole, Rock Sole, Yellowfin Sole, and AI Pacific Ocean Perch

Section 679.20(b)(1)(i) requires that NMFS reserve 15 percent of the TAC for each target species (except for pollock, fixed gear allocation of sablefish, and Amendment 80 species) in a non-specified reserve. Section 679.20(b)(1)(ii)(B) requires that NMFS allocate 20 percent of the fixed gear allocation of sablefish to the fixed-gear sablefish CDQ reserve for each subarea. Section 679.20(b)(1)(ii)(D) requires that NMFS allocate 7.5 percent of the trawl gear allocations of sablefish in the BS and AI and 10.7 percent of the BS Greenland turbot and arrowtooth flounder TACs to the respective CDQ reserves. Section 679.20(b)(1)(ii)(C) requires that NMFS allocate 10.7 percent of the TACs for Atka mackerel, AI Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod to the respective CDQ reserves. Section 679.20(b)(1)(ii)(A) also requires that 10 percent of the BS pollock TAC be allocated to the pollock CDQ directed fishing allowance (DFA). Section 679.20(b)(1)(ii)(A) requires that 10 percent of the AI pollock TAC be allocated to the pollock CDQ DFA. The entire Bogoslof District pollock TAC is allocated as an ICA pursuant to § 679.20(a)(5)(ii) because the Bogoslof District is closed to directed fishing for pollock by regulation (§ 679.22(a)(7)(B)). With the exception of the fixed gear sablefish CDQ reserve, the regulations do not further apportion the CDQ allocations by gear.

Pursuant to § 679.20(a)(5)(i)(A)(*1*), NMFS allocates a pollock ICA of 50,000 mt of the BS pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidental catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2000 through 2022. During this 23-year period, the pollock incidental catch ranged from a low of 2.2 percent in 2006 to a high of 4.6 percent in 2014, with a 23-year average of 3 percent. Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), NMFS establishes a pollock ICA of 2,500 mt of the AI pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidental catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2003 through 2022. During this 20-year period, the incidental catch of pollock ranged from a low of 5 percent in 2006 to a high of 17 percent in 2014, with a 20-year average of 9 percent.

After subtracting the 10.7 percent CDQ reserve and pursuant to § 679.20(a)(8) and (10), NMFS allocates ICAs of 3,000 mt of flathead sole, 6,000 mt of rock sole, 4,000 mt of yellowfin sole, 10 mt of WAI Pacific ocean perch, 60 mt of CAI Pacific ocean perch, 100 mt of Eastern Aleutian district (EAI) Pacific ocean perch, 20 mt of Western Aleutian district (WAI) Atka mackerel, 75 mt of Central Aleutian district (CAI)

Atka mackerel, and 800 mt of EAI and BS Atka mackerel. These ICA allowances are based on NMFS's examination of the incidental catch in other target fisheries from 2003 through 2022.

The regulations do not designate the remainder of the non-specified reserve by species or species group. Any amount of the reserve may be apportioned to a target species that contributed to the non-specified reserves during the year, provided that such apportionments are consistent with § 679.20(a)(3) and do not result in overfishing (see § 679.20(b)(1)(i)). The Regional Administrator has determined that the ITACs specified for one species group listed in Tables 1 and 2 need to be supplemented from the non-specified reserve because U.S. fishing vessels have demonstrated the capacity to catch the full TAC allocations. Therefore, in accordance with § 679.20(b), NMFS is apportioning the amounts shown in Table 3 from the non-specified reserve to increase the ITAC for AI ''other rockfish'' by 15 percent of the ''other rockfish'' TAC in 2023 and 2024.

TABLE 3—FINAL 2023 AND 2024 APPORTIONMENT OF NON-SPECIFIED RESERVES TO ITAC CATEGORIES

[Amounts are in metric tons]

Species-area or subarea	2023 ITAC	2023 reserve amount	2023 final TAC	2024 ITAC	2024 reserve amount	2024 final TAC
Other rockfish-Aleutian Islands subarea	323	57	380	323	57	380
Total	323	57	380	323	57	380

Allocation of Pollock TAC Under the American Fisheries Act (AFA)

Section 679.20(a)(5)(i)(A) requires that the BS pollock TAC be apportioned as a DFA, after subtracting 10 percent for the CDQ program and 50,000 mt for the ICA in both 2023 and 2024, as follows: 50 percent to the inshore sector, 40 percent to the catcher/processor (CP) sector, and 10 percent to the mothership sector. In the BS, 45 percent of the DFAs are allocated to the A season (January 20–June 10), and 55 percent of the DFAs are allocated to the B season (June 10–November 1) (§§ 679.20(a)(5)(i)(B)(*1*) and 679.23(e)(2)). The AI directed pollock fishery allocation to the Aleut Corporation is the amount of pollock TAC remaining in the AI after subtracting 1,900 mt for the CDQ DFA (10 percent) and 2,500 mt for the ICA (§ 679.20(a)(5)(iii)(B)(*2*)). In the AI, the total A season apportionment of the TAC (including the AI directed fishery allocation, the CDQ DFA, and the ICA) may not exceed 40 percent of the ABC for AI pollock, and the remainder of the TAC is allocated to the B season (§ 679.20(a)(5)(iii)(B)(*3*)). Tables 4 and 5 list these 2023 and 2024 amounts.

Section 679.20(a)(5)(iii)(B)(*6*) sets harvest limits for pollock in the A season (January 20 to June 10) in Areas 543, 542, and 541. NMFS establishes harvest limits for pollock in the A season in Area 541 of no more than 30 percent, in Area 542 of no more than 15 percent, and in Area 543 of no more than 5 percent of the Aleutian Islands pollock ABC.

Section 679.20(a)(5)(i)(A)(*4*) also includes several specific requirements regarding BS pollock allocations. First, it requires that 8.5 percent of the pollock allocated to the CP sector be available for harvest by AFA CVs with CP sector endorsements, unless the Regional Administrator receives a cooperative contract that allows for the distribution of harvest among AFA CPs and AFA CVs in a manner agreed to by all members. Second, AFA CPs not listed in the AFA are limited to harvesting not more than 0.5 percent of the pollock allocated to the CP sector. Tables 4 and 5 list the 2023 and 2024 allocations of pollock TAC. Table 20 lists the AFA CP prohibited species sideboard limits, and Tables 21 and 22 list the AFA CV groundfish and prohibited species sideboard limits. The tables for the pollock allocations to the BS inshore pollock cooperatives and open access sector will be posted on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-groundfish-fisheries-management.*

Tables 4 and 5 also list seasonal apportionments of pollock and harvest limits within the Steller Sea Lion Conservation Area (SCA). The harvest of pollock within the SCA, as defined at § 679.22(a)(7)(vii), is limited to no more than 28 percent of the annual pollock DFA before 12 p.m. (noon), April 1, as provided in § 679.20(a)(5)(i)(C). The A season pollock SCA harvest limit will be apportioned to each sector in proportion to each sector's allocated percentage of the DFA.

TABLE 4—FINAL 2023 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2023 Allocations	2023 A season [1]		2023 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea TAC [1]	1,300,000	n/a	n/a	n/a
CDQ DFA	130,000	58,500	36,400	71,500
ICA [1]	50,000	n/a	n/a	n/a
Total Bering Sea non-CDQ DFA	1,120,000	504,000	313,600	616,000
AFA Inshore	560,000	252,000	156,800	308,000
AFA Catcher/Processors [3]	448,000	201,600	125,440	246,400
Catch by CPs	409,920	184,464	n/a	225,456
Catch by CVs [3]	38,080	17,136	n/a	20,944
Unlisted CP Limit [4]	2,240	1,008	n/a	1,232
AFA Motherships	112,000	50,400	31,360	61,600

TABLE 4—FINAL 2023 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]—Continued

[Amounts are in metric tons]

Area and sector	2023 Allocations	2023 A season [1]		2023 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Excessive Harvesting Limit [5]	196,000	n/a	n/a	n/a
Excessive Processing Limit [6]	336,000	n/a	n/a	n/a
Aleutian Islands subarea ABC	43,413	n/a	n/a	n/a
Aleutian Islands subarea TAC [1]	19,000	n/a	n/a	n/a
CDQ DFA	1,900	1,856	n/a	44
ICA	2,500	1,250	n/a	1,250
Aleut Corporation	14,600	14,260	n/a	340
Area harvest limit [7]	n/a	n/a	n/a	n/a
541	13,024	n/a	n/a	n/a
542	6,512	n/a	n/a	n/a
543	2,171	n/a	n/a	n/a
Bogoslof District ICA [8]	300	n/a	n/a	n/a

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] Pursuant to § 679.20(a)(5)(i)(A), the Bering Sea subarea pollock TAC, after subtracting the CDQ DFA (10 percent) and the ICA (50,000 mt, 4.27 percent), is allocated as a DFA as follows: inshore sector—50 percent, catcher/processor sector (CP)—40 percent, and mothership sector—10 percent. In the Bering Sea subarea, 45 percent of the DFAs are allocated to the A season (January 20–June 10) and 55 percent of the DFAs are allocated to the B season (June 10–November 1). When the AI pollock ABC equals or exceeds 19,000 mt, the annual TAC is equal to 19,000 mt (§ 679.20(a)(5)(iii)(B)(*1*)). Pursuant to § 679.20(a)(5)(iii)(B)(*2*), the Aleutian Islands subarea pollock TAC, after subtracting first for the CDQ DFA (10 percent) and second for the ICA (2,500 mt), is allocated to the Aleut Corporation for a pollock directed fishery. In the Aleutian Islands subarea, the A season is allocated no more than 40 percent of the Aleutian Islands pollock ABC.

[2] In the Bering Sea subarea, pursuant to § 679.20(a)(5)(i)(C), no more than 28 percent of each sector's annual DFA may be taken from the SCA before 12 p.m. (noon), April 1.

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), 8.5 percent of the allocation to listed CPs shall be available for harvest only by eligible catcher vessels with a CP endorsement delivering to listed CPs, unless there is a CP sector cooperative for the year.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted catcher/processors are limited to harvesting not more than 0.5 percent of the catcher/processor sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30 percent of the sum of the non-CDQ pollock DFAs.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 of no more than 30 percent, in Area 542 of no more than 15 percent, and in Area 543 of no more than 5 percent of the Aleutian Islands pollock ABC.

[8] Pursuant to § 679.22(a)(7)(B), the Bogoslof District is closed to directed fishing for pollock. The amounts specified are for incidental catch only and are not apportioned by season or sector.

TABLE 5—FINAL 2024 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2024 Allocations	2024 A season [1]		2024 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea.				
TAC[1]	1,302,000	n/a	n/a	n/a
CDQ DFA	130,200	58,590	36,456	71,610
ICA [1]	50,000	n/a	n/a	n/a
Total Bering Sea non-CDQ DFA	1,121,800	504,810	314,104	616,990
AFA Inshore	560,900	252,405	157,052	308,495
AFA Catcher/Processors [3]	448,720	201,924	125,642	246,796
Catch by CPs	410,579	184,760	n/a	225,818
Catch by CVs [3]	38,141	17,164	n/a	20,978
Unlisted CP Limit [4]	2,244	1,010	n/a	1,234
AFA Motherships	112,180	50,481	31,410	61,699
Excessive Harvesting Limit [5]	196,315	n/a	n/a	n/a
Excessive Processing Limit [6]	336,540	n/a	n/a	n/a
Aleutian Islands subarea ABC	43,092	n/a	n/a	n/a
Aleutian Islands subarea TAC [1]	19,000	n/a	n/a	n/a
CDQ DFA	1,900	1,841	n/a	59
ICA	2,500	1,250	n/a	1,250
Aleut Corporation	14,600	14,146	n/a	454
Area harvest limit [7]	n/a	n/a	n/a	n/a
541	12,928	n/a	n/a	n/a
542	6,464	n/a	n/a	n/a
543	2,155	n/a	n/a	n/a

TABLE 5—FINAL 2024 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]—Continued

[Amounts are in metric tons]

Area and sector	2024 Allocations	2024 A season [1]		2024 B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bogoslof District ICA [8]	300	n/a	n/a	n/a

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] Pursuant to § 679.20(a)(5)(i)(A), the Bering Sea subarea pollock TAC, after subtracting the CDQ DFA (10 percent) and the ICA (50,000 mt, 4.27 percent), is allocated as a DFA as follows: inshore sector—50 percent, catcher/processor sector (CP)—40 percent, and mothership sector—10 percent. In the Bering Sea subarea, 45 percent of the DFAs are allocated to the A season (January 20–June 10) and 55 percent of the DFAs are allocated to the B season (June 10–November 1). When the AI pollock ABC equals or exceeds 19,000 mt, the annual TAC is equal to 19,000 mt (§ 679.20(a)(5)(iii)(B)(*1*)). Pursuant to § 679.20(a)(5)(iii)(B)(*2*), the Aleutian Islands subarea pollock TAC, after subtracting first for the CDQ DFA (10 percent) and second for the ICA (2,500 mt), is allocated to the Aleut Corporation for a pollock directed fishery. In the Aleutian Islands subarea, the A season is allocated no more than 40 percent of the Aleutian Islands pollock ABC.

[2] In the Bering Sea subarea, pursuant to § 679.20(a)(5)(i)(C), no more than 28 percent of each sector's annual DFA may be taken from the SCA before 12 p.m. (noon), April 1.

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), 8.5 percent of the allocation to listed CPs shall be available for harvest only by eligible catcher vessels with a CP endorsement delivering to listed CPs, unless there is a CP sector cooperative for the year.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted catcher/processors are limited to harvesting not more than 0.5 percent of the catcher/processor sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30 percent of the sum of the non-CDQ pollock DFAs.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 of no more than 30 percent, in Area 542 of no more than 15 percent, and in Area 543 of no more than 5 percent of the Aleutian Islands pollock ABC.

[8] Pursuant to § 679.22(a)(7)(B), the Bogoslof District is closed to directed fishing for pollock. The amounts specified are for incidental catch only and are not apportioned by season or sector.

Allocation of the Atka Mackerel TACs

Section 679.20(a)(8) allocates the Atka mackerel TACs to the Amendment 80 and BSAI trawl limited access sectors, after subtracting the CDQ reserves, ICAs for the BSAI trawl limited access sector and non-trawl gear sector, and the jig gear allocation (Tables 6 and 7). The percentage of the ITAC for Atka mackerel allocated to the Amendment 80 and BSAI trawl limited access sectors is listed in Table 33 to 50 CFR part 679 and in § 679.91. Pursuant to § 679.20(a)(8)(i), up to 2 percent of the EAI and the BS Atka mackerel TAC may be allocated to vessels using jig gear. The percent of this allocation is recommended annually by the Council based on several criteria, including, among other criteria, the anticipated harvest capacity of the jig gear fleet. The Council recommended, and NMFS approves, a 0.5 percent allocation of the Atka mackerel TAC in the EAI and BS to the jig gear sector in 2023 and 2024.

Section 679.20(a)(8)(ii)(A) apportions the Atka mackerel TAC, after subtraction of the jig gear allocation, into two equal seasonal allowances. Section 679.23(e)(3) sets the first seasonal allowance for directed fishing with trawl gear from January 20 through June 10 (A season), and the second seasonal allowance from June 10 through December 31 (B season). Section 679.23(e)(4)(iii) applies Atka mackerel seasons to CDQ Atka mackerel trawl fishing. Within any fishing year, any under harvest or over harvest of a seasonal allowance may be added to or subtracted from a subsequent seasonal allowance (§ 679.20(a)(8)(ii)(B)). The ICAs and jig gear allocations are not apportioned by season.

Sections 679.20(a)(8)(ii)(C)(*1*)(*i*) and (*ii*) limits Atka mackerel catch within waters 0 nautical miles (nmi) to 20 nmi of Steller sea lion sites listed in Table 6 to 50 CFR part 679 and located west of 178° W longitude to no more than 60 percent of the annual TACs in Areas 542 and 543, and equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3). Section 679.20(a)(8)(ii)(C)(*2*) requires that the annual TAC in Area 543 will be no more than 65 percent of the ABC in Area 543. Section 679.20(a)(8)(ii)(D) requires that any unharvested Atka mackerel A season allowance that is added to the B season be prohibited from being harvested within waters 0 nmi to 20 nmi of Steller sea lion sites listed in Table 6 to 50 CFR part 679 and located in Areas 541, 542, and 543.

Tables 6 and 7 list these 2023 and 2024 Atka mackerel seasonal and area allowances, and the sector allocations. One Amendment 80 cooperative has formed for the 2023 fishing year. Because all Amendment 80 vessels are part of the sole Amendment 80 cooperative, no allocation to the Amendment 80 limited access sector is required for 2023. The 2024 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

TABLE 6—FINAL 2023 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE, AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2023 Allocation by area		
		Eastern Aleutian district/Bering Sea	Central Aleutian district [5]	Western Aleutian district
TAC	n/a	27,260	17,351	24,671
CDQ reserve	Total	2,917	1,857	2,640
	A	1,458	928	1,320
	Critical Habitat	n/a	557	792
	B	1,458	928	1,320
	Critical Habitat	n/a	557	792
Non-CDQ TAC	n/a	24,343	15,494	22,031
ICA	Total	800	75	20
Jig [6]	Total	118	.....	.....
BSAI trawl limited access	Total	2,343	1,542	.....
	A	1,171	771	.....
	Critical Habitat	n/a	463	.....
	B	1,171	771	.....
	Critical Habitat	n/a	463	.....
Amendment 80 sector	Total	21,083	13,877	22,011
	A	10,541	6,939	11,006
	Critical Habitat	n/a	4,163	6,603
	B	10,541	6,939	11,006
	Critical Habitat	n/a	4,163	6,603

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, ICAs, and jig gear allocation, to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in Table 33 to 50 CFR part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see § 679.20(b)(1)(ii)(C)).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10 and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of Steller sea lion protection areas; section 679.20(a)(8)(ii)(C)(*1*)(*ii*) equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3); and section 679.20(a)(8)(ii)(C)(*2*) requires that the TAC in Area 543 shall be no more than 65 percent of ABC in Area 543.

[6] Sections 679.2 and 679.20(a)(8)(i) require that up to 2 percent of the Eastern Aleutian Islands District and the Bering Sea subarea TAC be allocated to jig gear after subtracting the CDQ reserve and the ICA. NMFS sets the amount of this allocation for 2023 at 0.5 percent. The jig gear allocation is not apportioned by season.

TABLE 7—FINAL 2024 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE, AND AMENDMENT 80 ALLOCATION OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2024 Allocation by area		
		Eastern Aleutian district/Bering Sea [5]	Central Aleutian district [5]	Western Aleutian district [5]
TAC	n/a	30,000	15,218	21,637
CDQ reserve	Total	3,210	1,628	2,315
	A	1,605	814	1,158
	Critical Habitat	n/a	488	695
	B	1,605	814	1,158
	Critical Habitat	n/a	488	695
non-CDQ TAC	n/a	26,790	13,590	19,322
ICA	Total	800	75	20
Jig [6]	Total	130	.....	.....
BSAI trawl limited access	Total	2,586	1,351	.....
	A	1,293	676	.....
	Critical Habitat	n/a	405	.....
	B	1,293	676	.....
	Critical Habitat	n/a	405	.....
Amendment 80 sectors [7]	Total	23,274	12,163	19,302
	A	11,637	6,082	9,651
	Critical Habitat	n/a	3,649	5,791
	B	11,637	6,082	9,651

TABLE 7—FINAL 2024 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE, AND AMENDMENT 80 ALLOCATION OF THE BSAI ATKA MACKEREL TAC—Continued

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2024 Allocation by area		
		Eastern Aleutian district/Bering Sea [5]	Central Aleutian district [5]	Western Aleutian district [5]
	Critical Habitat	n/a	3,649	5,791

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, ICAs, and jig gear allocation, to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in Table 33 to 50 CFR part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see § 679.20(b)(1)(ii)(C)).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10 and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of Steller sea lion protection areas; section 679.20(a)(8)(ii)(C)(*1*)(*ii*) equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3); and section 679.20(a)(8)(ii)(C)(*2*) requires that the TAC in Area 543 shall be no more than 65 percent of ABC in Area 543.

[6] Sections 679.2 and 679.20(a)(8)(i) requires that up to 2 percent of the Eastern Aleutian Islands District and the Bering Sea subarea TAC be allocated to jig gear after subtracting the CDQ reserve and the ICA. NMFS sets the amount of this allocation for 2024 at 0.5 percent. The jig gear allocation is not apportioned by season.

[7] The 2024 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

Allocation of the Pacific Cod TAC

The Council separated BSAI subarea OFLs, ABCs, and TACs for Pacific cod in 2014 (79 FR 12108, March 4, 2014). Section 679.20(b)(1)(ii)(C) allocates 10.7 percent of the BS TAC and the AI TAC to the CDQ program. After CDQ allocations have been deducted from the respective BS and AI Pacific cod TACs, the remaining BSAI Pacific cod TACs are combined for calculating further BSAI Pacific cod sector allocations. If the non-CDQ Pacific cod TAC is or will be reached in either the BS or the AI subareas, NMFS will prohibit non-CDQ directed fishing for Pacific cod in that subarea as provided in § 679.20(d)(1)(iii).

Section 679.20(a)(7)(ii) allocates to the non-CDQ sectors the Pacific cod TAC in the combined BSAI, after subtracting 10.7 percent for the CDQ program, as follows: 1.4 percent to vessels using jig gear; 2.0 percent to hook-and-line or pot CVs less than 60 ft (18.3 m) length overall (LOA); 0.2 percent to hook-and-line CVs greater than or equal to 60 ft (18.3 m) LOA; 48.7 percent to hook-and-line CPs; 8.4 percent to pot CVs greater than or equal to 60 ft (18.3 m) LOA; 1.5 percent to pot CPs; 2.3 percent to AFA trawl CPs; 13.4 percent to Amendment 80 sector; and 22.1 percent to trawl CVs. The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. For 2023 and 2024, the Regional Administrator establishes an ICA of 500 mt based on anticipated incidental catch by these sectors in other fisheries. During the fishing year, NMFS may reallocate unharvested Pacific cod among sectors, consistent with the reallocation hierarchy set forth at § 679.20(a)(7)(iii).

The ITAC allocation of Pacific cod to the Amendment 80 sector is established in Table 33 to 50 CFR part 679 and § 679.91. One Amendment 80 cooperative has formed for the 2023 fishing year. Because all Amendment 80 vessels are part of the sole Amendment 80 cooperative, no allocation to the Amendment 80 limited access sector is required for 2023. The 2024 allocations for Pacific cod between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

The sector allocations of Pacific cod are apportioned into seasonal allowances to disperse the Pacific cod fisheries over the fishing year (see §§ 679.20(a)(7)(i)(B), 679.20(a)(7)(iv)(A), and 679.23(e)(5)). Tables 8 and 9 list the non-CDQ sector and seasonal allowances. In accordance with § 679.20(a)(7)(iv)(B) and (C), any unused portion of a non-CDQ Pacific cod seasonal allowance for any sector, except the jig sector, will become available at the beginning of that sector's next seasonal allowance. Section 679.20(a)(7)(i)(B) sets forth the CDQ Pacific cod gear allowances by season, and CDQ groups are prohibited from exceeding those seasonal allowances (§ 679.7(d)(6)).

Section 679.20(a)(7)(vii) requires that the Regional Administrator establish an Area 543 Pacific cod harvest limit based on Pacific cod abundance in Area 543 as determined by the annual stock assessment process. Based on the 2022 stock assessment, the Regional Administrator determined for 2023 and 2024 the estimated amount of Pacific cod abundance in Area 543 is 15.7 percent of the total AI abundance. To calculate the Area 543 Pacific cod harvest limit, NMFS first subtracts the State GHL Pacific cod amount from the AI Pacific cod ABC. Then NMFS determines the harvest limit in Area 543 by multiplying the percentage of Pacific cod estimated in Area 543 (15.7 percent) by the remaining ABC for AI Pacific cod. Based on these calculations, the Area 543 harvest limit is 2,233 mt for 2023 and 2024.

On March 21, 2019, the final rule adopting Amendment 113 to the FMP (81 FR 84434, November 23, 2016) was vacated by the U.S. District Court for the District of Columbia (*Groundfish Forum* v. *Ross,* No. 16–2495 (D.D.C. March 21, 2019)), and the corresponding regulations implementing Amendment 113 are no longer in effect. Therefore, this final rule is not specifying amounts for the AI Pacific Cod Catcher Vessel Harvest Set-Aside Program (see § 679.20(a)(7)(viii)). NMFS anticipates that in 2024 the regulations at § 679.20(a)(7)(viii) will be removed through implementation of the PCTC Program, if Amendment 122 and its regulations are approved by the Secretary of Commerce (described above

in Other Actions Affecting the 2023 and 2024 Harvest Specifications).

Based on the final 2023 and 2024 Pacific cod TACs, Table 8 and Table 9 list the CDQ and non-CDQ TAC amounts; non-CDQ seasonal allowances by gear; the sector allocations of Pacific cod; and the seasons set forth at § 679.23(e)(5).

TABLE 8—FINAL 2023 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI PACIFIC COD TAC

[Amounts are in metric tons]

Sector	Percent	2023 Share of total	2023 Share of sector total	2023 Seasonal apportionment	
				Season	Amount
BS TAC	n/a	127,409	n/a	n/a	n/a
BS CDQ	n/a	13,633	n/a	see § 679.20(a)(7)(i)(B)	n/a
BS non-CDQ TAC	n/a	113,776	n/a	n/a	n/a
AI TAC	n/a	8,425	n/a	n/a	n/a
AI CDQ	n/a	901	n/a	see § 679.20(a)(7)(i)(B)	n/a
AI non-CDQ TAC	n/a	7,524	n/a	n/a	n/a
Area 543 Western Aleutian Island Limit	n/a	2,233	n/a	n/a	n/a
Total BSAI non-CDQ TAC [1]	100	121,300	n/a	n/a	n/a
Total hook-and-line/pot gear	60.8	73,750	n/a	n/a	n/a
Hook-and-line/pot ICA [2]	n/a	500	n/a	see § 679.20(a)(7)(ii)(B)	n/a
Hook-and-line/pot sub-total	n/a	73,250	n/a	n/a	n/a
Hook-and-line catcher/processor	48.7	n/a	58,672	Jan 1–Jun 10	29,923
				Jun 10–Dec 31	28,750
Hook-and-line catcher vessel ≥60 ft LOA	0.2	n/a	241	Jan 1–Jun 10	123
				Jun 10–Dec 31	118
Pot catcher/processor	1.5	n/a	1,807	Jan 1–Jun 10	922
				Sept 1–Dec 31	886
Pot catcher vessel ≥60 ft LOA	8.4	n/a	10,120	Jan 1–Jun 10	5,161
				Sept 1–Dec 31	4,959
Catcher vessel <60 ft LOA using hook-and-line or pot gear.	2.0	n/a	2,410	n/a	n/a
Trawl catcher vessel	22.1	26,807	n/a	Jan 20–Apr 1	19,837
				Apr 1–Jun 10	
				Jun 10–Nov 1	2,949
					4,021
AFA trawl catcher/processor	2.3	2,790	n/a	Jan 20–Apr 1	2,092
				Apr 1–Jun 10	
				Jun 10–Nov 1	697
Amendment 80	13.4	16,254	n/a	Jan 20–Apr 1	12,191
				Apr 1–Jun 10	
				Jun 10–Dec 31	4,064
Jig	1.4	1,698	n/a	Jan 1–Apr 30	1,019
				Apr 30–Aug 31	340
				Aug 31–Dec 31	340

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] The sector allocations and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs, after the subtraction of the reserves for the CDQ program. If the TAC for Pacific cod in either the AI or BS is or will be reached, then directed fishing for non-CDQ Pacific cod in that subarea will be prohibited, even if a BSAI allowance remains (§ 679.20(d)(1)(iii)).

[2] The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator approves an ICA of 500 mt for 2023 based on anticipated incidental catch by these sectors in other fisheries.

TABLE 9—FINAL 2024 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI PACIFIC COD TAC

[Amounts are in metric tons]

Sector	Percent	2024 Share total	2024 Share of sector total	2024 Seasonal apportionment	
				Season	Amount
BS TAC	n/a	123,295	n/a	n/a	n/a
BS CDQ	n/a	13,193	n/a	see § 679.20(a)(7)(i)(B)	n/a
BS non-CDQ TAC	n/a	110,102	n/a	n/a	n/a
AI TAC	n/a	8,425	n/a	n/a	n/a
AI CDQ	n/a	901	n/a	see § 679.20(a)(7)(i)(B)	n/a
AI non-CDQ TAC	n/a	7,524	n/a	n/a	n/a
Area 543 Western Aleutian Island Limit	n/a	2,233	n/a	n/a	n/a

TABLE 9—FINAL 2024 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI PACIFIC COD TAC—Continued

[Amounts are in metric tons]

Sector	Percent	2024 Share total	2024 Share of sector total	2024 Seasonal apportionment	
				Season	Amount
Total BSAI non-CDQ TAC [1]	n/a	117,626	n/a	n/a	n/a
Total hook-and-line/pot gear	60.8	71,517	n/a	n/a	n/a
Hook-and-line/pot ICA [2]	n/a	500	n/a	see § 679.20(a)(7)(ii)(B)	n/a
Hook-and-line/pot sub-total	n/a	71,017	n/a	n/a	n/a
Hook-and-line catcher/processor	48.7	n/a	56,883	Jan 1–Jun 10	29,011
				Jun 10–Dec 31	27,873
Hook-and-line catcher vessel ≥60 ft LOA	0.2	n/a	234	Jan 1–Jun 10	119
				Jun 10–Dec 31	114
Pot catcher/processor	1.5	n/a	1,752	Jan 1–Jun 10	894
				Sept 1–Dec 31	859
Pot catcher vessel ≥60 ft LOA	8.4	n/a	9,812	Jan 1–Jun 10	5,004
				Sept 1–Dec 31	4,808
Catcher vessel <60 ft LOA using hook-and-line or pot gear.	2.0	n/a	2,336	n/a	n/a
Trawl catcher vessel	22.1	25,995	n/a	Jan 20–Apr 1	19,237
				Apr 1–Jun 10	3,899
				Jun 10–Nov 1	2,859
AFA trawl catcher/processor	2.3	2,705	n/a	Jan 20–Apr 1	2,029
				Apr 1–Jun 10	676
				Jun 10–Nov 1	
Amendment 80	13.4	15,762	n/a	Jan 20–Apr 1	11,821
				Apr 1–Jun 10	3,940
				Jun 10-Dec 31	
Jig	1.4	1,647	n/a	Jan 1–Apr 30	988
				Apr 30–Aug 31	329
				Aug 31–Dec 31	329

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] The sector allocations and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs, after the subtraction of the reserves for the CDQ program. If the TAC for Pacific cod in either the AI or BS is or will be reached, then directed fishing for non-CDQ Pacific cod in that subarea will be prohibited, even if a BSAI allowance remains (§ 679.20(d)(1)(iii)).

[2] The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator approves an ICA of 500 mt for 2024 based on anticipated incidental catch by these sectors in other fisheries.

Sablefish Gear Allocation

Sections 679.20(a)(4)(iii) and (iv) require allocation of the sablefish TAC for the BS and AI subareas between the trawl gear and fixed gear sectors. Gear allocations of the sablefish TAC for the BS are 50 percent for trawl gear and 50 percent for fixed gear. Gear allocations of the TAC for the AI are 25 percent for trawl gear and 75 percent for fixed gear. Section 679.20(b)(1)(ii)(B) requires that NMFS apportions 20 percent of the fixed gear allocation of sablefish TAC to the CDQ reserve for each subarea. Also, § 679.20(b)(1)(ii)(D)(*1*) requires that in the BS and AI 7.5 percent of the trawl gear allocation of sablefish TAC from the non-specified reserve, established under § 679.20(b)(1)(i), be assigned to the CDQ reserve.

The Council recommended that only trawl sablefish TAC be established biennially. The harvest specifications for the fixed gear sablefish Individual Fishing Quota (IFQ) fisheries are limited to the 2023 fishing year to ensure those fisheries are conducted concurrently with the halibut IFQ fishery. Concurrent sablefish and halibut IFQ fisheries reduce the potential for discards of halibut and sablefish in those fisheries. The sablefish IFQ fisheries remain closed at the beginning of each fishing year until the final harvest specifications for the sablefish IFQ fisheries are in effect. Table 10 lists the 2023 and 2024 gear allocations of the sablefish TAC and CDQ reserve amounts.

TABLE 10—FINAL 2023 AND 2024 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2023 Share of TAC	2023 ITAC	2023 CDQ reserve	2024 Share of TAC	2024 ITAC	2024 CDQ reserve
Bering Sea.							
Trawl gear [1]	50	3,998	3,398	300	4,838	4,112	363
Fixed gear [2]	50	3,998	3,198	800	n/a	n/a	n/a

TABLE 10—FINAL 2023 AND 2024 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS—Continued

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2023 Share of TAC	2023 ITAC	2023 CDQ reserve	2024 Share of TAC	2024 ITAC	2024 CDQ reserve
Total	100	7,996	6,597	1,099	4,838	4,112	363
Aleutian Islands.							
Trawl gear [1]	25	2,110	1,794	158	2,448	2,081	184
Fixed gear [2]	75	6,330	5,064	1,266	n/a	n/a	n/a
Total	100	8,440	6,858	1,424	2,448	2,081	184

Note: Seasonal or sector apportionments may not total precisely due to rounding.

[1] For the sablefish TAC allocated to vessels using trawl gear, 15 percent of TAC is apportioned to the non-specified reserve (§ 679.20(b)(1)(i)). The ITAC for vessels using trawl gear is the remainder of the TAC after subtracting this reserve. In the BS and AI, 7.5 percent of the trawl gear allocation of the TAC is assigned from the non-specified reserve to the CDQ reserve (§ 679.20(b)(1)(ii)(D)(*1*)).

[2] For the portion of the sablefish TAC allocated to vessels using fixed gear, 20 percent of the allocated TAC for the BS and AI is reserved for use by CDQ participants (§ 679.20(b)(1)(ii)(B)). The ITAC for vessels using fixed gear is the remainder of the TAC after subtracting the CDQ reserve for each subarea. The Council recommended that specifications for the fixed gear sablefish IFQ fisheries be limited to 1 year.

Allocation of the AI Pacific Ocean Perch, and BSAI Flathead Sole, Rock Sole, and Yellowfin Sole TACs

Sections 679.20(a)(10)(i) and (ii) require that NMFS allocate AI Pacific ocean perch and BSAI flathead sole, rock sole, and yellowfin sole ITACs between the Amendment 80 sector and the BSAI trawl limited access sector, after subtracting 10.7 percent for the CDQ reserves and ICAs for the BSAI trawl limited access sector and vessels using non-trawl gear. The allocations of the ITACs for AI Pacific ocean perch and BSAI flathead sole, rock sole, and yellowfin sole to the Amendment 80 sector are established in accordance with Tables 33 and 34 to 50 CFR part 679 and § 679.91.

One Amendment 80 cooperative has formed for the 2023 fishing year. Because all Amendment 80 vessels are part of the sole Amendment 80 cooperative, no allocation to the Amendment 80 limited access sector is required for 2023. The 2024 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023. Tables 11 and 12 list the 2023 and 2024 allocations of the AI Pacific ocean perch and BSAI flathead sole, rock sole, and yellowfin sole TACs.

TABLE 11—FINAL 2023 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian district	Central Aleutian district	Western Aleutian district	BSAI	BSAI	BSAI
TAC	8,152	5,648	12,000	35,500	66,000	230,000
CDQ	872	604	1,284	3,799	7,062	24,610
ICA	100	60	10	3,000	6,000	4,000
BSAI trawl limited access	718	498	214	.....	.....	45,498
Amendment 80	6,462	4,485	10,492	28,702	52,938	155,892

Note: Sector apportionments may not total precisely due to rounding.

TABLE 12—FINAL 2024 COMMUNITY DEVELOPMENT QUOTA (CDC) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian district	Central Aleutian district	Western Aleutian district	BSAI	BSAI	BSAI
TAC	8,013	5,551	13,000	35,500	66,000	230,656
CDQ	857	594	1,391	3,799	7,062	24,680
ICA	100	60	10	3,000	6,000	4,000
BSAI trawl limited access	706	490	232	.....	.....	45,733
Amendment 80 [1]	6,350	4,407	11,367	28,702	52,938	156,243

Note: Sector apportionments may not total precisely due to rounding.

[1] The 2024 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

Section 679.2 defines the ABC surplus for flathead sole, rock sole, and yellowfin sole as the difference between the annual ABC and TAC for each species. Section 679.20(b)(1)(iii) establishes ABC reserves for flathead sole, rock sole, and yellowfin sole. The ABC surpluses and the ABC reserves are necessary to mitigate the operational variability, environmental conditions, and economic factors that may constrain the CDQ groups and the Amendment 80 cooperatives from fully harvesting their allocations and to improve the likelihood of achieving and maintaining, on a continuing basis, the optimum yield in the BSAI groundfish fisheries. NMFS, after consultation with the Council, may set the ABC reserve at or below the ABC surplus for each species, thus maintaining the TAC at or below ABC limits. An amount equal to 10.7 percent of the ABC reserves will be allocated as CDQ ABC reserves for flathead sole, rock sole, and yellowfin sole. Section 679.31(b)(4) establishes the annual allocations of CDQ ABC reserves among the CDQ groups. The Amendment 80 ABC reserves are the ABC reserves minus the CDQ ABC reserves. Section 679.91(i)(2) establishes Amendment 80 cooperatives ABC reserve to be the ratio of each cooperatives' quota share units and the total Amendment 80 quota share units, multiplied by the Amendment 80 ABC reserve for each respective species. Table 13 lists the 2023 and 2024 ABC surplus and ABC reserves for BSAI flathead sole, rock sole, and yellowfin sole.

TABLE 13—FINAL 2023 AND 2024 ABC SURPLUS, ABC RESERVES, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	2023 Flathead sole	2023 Rock sole	2023 Yellowfin sole	2024 [1] Flathead sole	2024 [1] Rock sole	2024 [1] Yellowfin sole
ABC	65,344	121,719	378,499	66,927	119,969	462,890
TAC	35,500	66,000	230,000	35,500	66,000	230,656
ABC surplus	29,844	55,719	148,499	31,427	53,969	232,234
ABC reserve	29,844	55,719	148,499	31,427	53,969	232,234
CDQ ABC reserve	3,193	5,962	15,889	3,363	5,775	24,849
Amendment 80 ABC reserve	26,651	49,757	132,610	28,064	48,194	207,385

[1] The 2024 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

PSC Limits for Halibut, Salmon, Crab, and Herring

Section 679.21, at paragraphs (b), (e), (f), and (g), sets forth the BSAI PSC limits. Pursuant to § 679.21(b)(1), the annual BSAI halibut PSC limits total 3,515 mt. Section 679.21(b)(1) allocates 315 mt of the halibut PSC limit as the PSQ reserve for use by the groundfish CDQ Program, 1,745 mt of the halibut PSC limit for the Amendment 80 sector, 745 mt of the halibut PSC limit for the BSAI trawl limited access sector, and 710 mt of the halibut PSC limit for the BSAI non-trawl sector.

Section 679.21(b)(1)(iii)(A) and (B) requires apportionment of the BSAI non-trawl halibut PSC limit into PSC allowances among six fishery categories in Table 17, and § 679.21(b)(1)(ii)(A) and (B), (e)(3)(i)(B), and (e)(3)(iv) requires apportionment of the trawl PSC limits in Tables 15 and 16 into PSC allowances among seven fishery categories. These apportionments into PSC allowances are based on the fishery categories' share of anticipated halibut PSC during the fishing year and the need to optimize the amount of total groundfish harvested under the halibut PSC limit for the non-trawl and trawl sectors.

Pursuant to Section 3.6 of the FMP, the Council recommends, and NMFS agrees, that certain specified non-trawl fisheries be exempt from the halibut PSC limit. As in past years, after consultation with the Council, NMFS exempts the pot gear fishery, the jig gear fishery, and the sablefish IFQ fixed gear fishery categories from halibut bycatch restrictions for the following reasons: (1) the pot gear fisheries have low halibut bycatch mortality; (2) NMFS estimates halibut mortality for the jig gear fleet to be negligible because of the small size of the fishery and the selectivity of the gear; and (3) the sablefish and halibut IFQ fisheries have low halibut bycatch mortality because the IFQ program requires that legal-size halibut be retained by vessels using fixed gear if a halibut IFQ permit holder or a hired master is aboard and is holding unused halibut IFQ for that vessel category and the IFQ regulatory area in which the vessel is operating (§ 679.7(f)(11)).

The 2022 total groundfish catch for the pot gear fishery in the BSAI was 21,177 mt, with an associated halibut bycatch mortality of 25 mt. The 2022 jig gear fishery harvested no groundfish. Most vessels in the jig gear fleet are exempt from observer coverage requirements. As a result, observer data are not available on halibut bycatch in the jig gear fishery. As mentioned above, NMFS estimates a negligible amount of halibut bycatch mortality because of the selective nature of jig gear and the low mortality rate of halibut caught with jig gear and released.

Under § 679.21(f)(2), NMFS annually allocates portions of either 33,318, 45,000, 47,591, or 60,000 Chinook salmon PSC limits among the AFA sectors, depending on past bycatch performance, on whether Chinook salmon bycatch incentive plan agreements (IPAs) are formed and approved by NMFS, and on whether NMFS determines it is a low Chinook salmon abundance year. NMFS will determine that it is a low Chinook salmon abundance year when abundance of Chinook salmon in western Alaska is less than or equal to 250,000 Chinook salmon. The State of Alaska provides to NMFS an estimate of Chinook salmon abundance using the 3-System Index for western Alaska based on the Kuskokwim, Unalakleet, and Upper Yukon aggregate stock grouping.

If an AFA sector participates in an approved IPA and has not exceeded its performance standard under § 679.21(f)(6), and if it is not a low Chinook salmon abundance year, then NMFS will allocate a portion of the 60,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(A). If no IPA is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), and if it is not a low abundance year, then NMFS will allocate a portion of the 47,591 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(C). If an AFA sector participates in an approved IPA and has not exceeded its

performance standard under § 679.21(f)(6), in a low abundance year, then NMFS will allocate a portion of the 45,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(B). If no IPA is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), and if in a low abundance year, then NMFS will allocate a portion of the 33,318 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(D).

NMFS has determined that 2022 was a low Chinook salmon abundance year, based on the State's estimate that Chinook salmon abundance in western Alaska is less than 250,000 Chinook salmon. Therefore, in 2023, the Chinook salmon PSC limit is 45,000 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(B). The AFA sector Chinook salmon PSC allocations are also seasonally apportioned with 70 percent for the A season pollock fishery, and 30 percent for the B season pollock fishery (§§ 679.21(f)(3)(i) and 679.23(e)(2)). In 2023, the Chinook salmon bycatch performance standard under § 679.21(f)(6) is 33,318 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(D).

NMFS publishes the approved IPAs, allocations, and reports at *https://alaskafisheries.noaa.gov/sustainablefisheries/bycatch/default.htm.*

Section 679.21(g)(2)(i) specifies 700 fish as the 2023 and 2024 Chinook salmon PSC limit for the AI pollock fishery. Section 679.21(g)(2)(ii) allocates 7.5 percent, or 53 Chinook salmon, as the AI PSQ reserve for the CDQ program, and allocates the remaining 647 Chinook salmon to the non-CDQ fisheries.

Section 679.21(f)(14)(i) specifies 42,000 fish as the 2023 and 2024 non-Chinook salmon PSC limit for vessels using trawl gear from August 15 through October 14 in the Catcher Vessel Operational Area (CVOA). Section 679.21(f)(14)(ii) allocates 10.7 percent, or 4,494 non-Chinook salmon, in the CVOA as the PSQ reserve for the CDQ program, and allocates the remaining 37,506 non-Chinook salmon in the CVOA to the non-CDQ fisheries. Section 679.21(f)(14)(iv) exempts from closures in the Chum Salmon Savings Area trawl vessels participating in directed fishing for pollock and operating under an IPA approved by NMFS.

PSC limits for crab and herring are specified annually based on abundance and spawning biomass. Section 679.21(e)(3)(i)(A)(*1*) allocates 10.7 percent from each trawl gear PSC limit specified for crab as a PSQ reserve for use by the groundfish CDQ program.

Based on the most recent (2022) survey data, the red king crab mature female abundance is estimated at 8.004 million red king crabs, and the effective spawning biomass is estimated at 19.607 million lbs (8,894 mt). Based on the criteria set out at § 679.21(e)(1)(i), the 2023 and 2024 PSC limit of red king crab in Zone 1 for trawl gear is 32,000 animals. This limit derives from the mature female abundance estimate below 8.4 million mature red king crab.

Section 679.21(e)(3)(ii)(B)(*2*) establishes criteria under which NMFS must specify an annual red king crab bycatch limit for the Red King Crab Savings Subarea (RKCSS) if the State has established a GHL fishery for red king crab in the Bristol Bay area in the previous year. The State's Department of Fish and Game (ADF&G) and NMFS have reviewed the final 2022 NMFS trawl survey data for the Bristol Bay red king crab stock. The stock is estimated to be below the regulatory threshold for opening a fishery. Therefore, the State did not establish a GHL for the Bristol Bay red king crab fishery, and the fishery will remain closed for the 2022/2023 crab season. Since the State did not establish a GHL, NMFS and the Council will not specify an amount of the red king crab bycatch limit, annually established under § 679.21(e)(1)(i), for the RKCSS for 2023. Also, NMFS closed directed fishing for groundfish for vessels using non-pelagic trawl gear in the RKCSS for 2023 (88 FR 3930, January 23, 2023). NMFS and the Council will assess the RKCSS bycatch limit and closure for 2024 based on whether the State's ADF&G establishes a GHL for the 2023/2024 red king crab fishery in the Bristol Bay area.

Based on the most recent (2022) survey data, Tanner crab (*Chionoecetes bairdi*) abundance is estimated at 381 million animals. Pursuant to criteria set out at § 679.21(e)(1)(ii), the calculated 2023 and 2024 *C. bairdi* crab PSC limit for trawl gear is 830,000 animals in Zone 1, and 2,520,000 animals in Zone 2. The limit in Zone 1 is based on the abundance of *C. bairdi* estimated at 381 million animals, which is greater than 270 million animals but less than 400 million animals. The limit in Zone 2 is based on the abundance of *C. bairdi* estimated at 381 million animals, which is greater than 290 million animals but less than 400 million animals.

Pursuant to § 679.21(e)(1)(iii), the PSC limit for trawl gear for snow crab (*Chionoecetes opilio*) is based on total abundance as indicated by the NMFS annual bottom trawl survey. The *C. opilio* crab PSC limit in the *C. opilio* bycatch limitation zone (COBLZ) is set at 0.1133 percent of the BS abundance index minus 150,000 crabs, unless the minimum or maximum PSC limit applies. Based on the most recent (2022) survey estimate of 2.584 billion animals, the calculated *C. opilio* crab PSC limit is 2,927,672 animals. Because 0.1133 percent multiplied by the total abundance is less than 4.5 million, the minimum PSC limit applies and the PSC limit will be 4.350 million animals.

Pursuant to § 679.21(e)(1)(v), the PSC limit of Pacific herring caught while conducting any trawl operation for BSAI groundfish is 1 percent of the annual eastern BS herring biomass. The best estimate of 2023 and 2024 herring biomass is 344,379 mt. This amount was developed by ADF&G based on biomass for spawning aggregations. Therefore, the herring PSC limit for 2023 and 2024 is 3,444 mt for all trawl gear as listed in Tables 14 and 15.

Section 679.21(e)(3)(i)(A) requires that crab PSQ reserves be subtracted from the total trawl gear crab PSC limits. The crab and halibut PSC limits apportioned to the Amendment 80 and BSAI trawl limited access sectors are listed in Table 35 to 50 CFR part 679. The resulting 2023 and 2024 allocations of PSC limit to CDQ PSQ reserves, the Amendment 80 sector, and the BSAI trawl limited access sector are listed in Table 14. Pursuant to §§ 679.21(b)(1)(i), 679.21(e)(3)(vi), and 679.91(d) through (f), crab and halibut trawl PSC limits assigned to the Amendment 80 sector are then further allocated to Amendment 80 cooperatives as cooperative quota. Crab and halibut PSC cooperative quota assigned to Amendment 80 cooperatives is not allocated to specific fishery categories. In 2023, there are no vessels in the Amendment 80 limited access sector and there is one Amendment 80 cooperative. The 2024 PSC allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2023.

Sections 679.21(b)(2) and (e)(5) authorize NMFS, after consulting with the Council, to establish seasonal apportionments of halibut and crab PSC amounts for the BSAI trawl limited access and non-trawl sectors to maximize the ability of the fleet to harvest the available groundfish TAC and to minimize bycatch. The factors to be considered are: (1) seasonal distribution of prohibited species, (2) seasonal distribution of target groundfish species relative to prohibited species distribution, (3) PSC bycatch needs on a seasonal basis relevant to

prohibited species biomass and expected catches of target groundfish species, (4) expected variations in bycatch rates throughout the year, (5) expected changes in directed groundfish fishing seasons, (6) expected start of fishing effort, and (7) economic effects of establishing seasonal prohibited species apportionments on segments of the target groundfish industry. Based on this criteria, the Council recommended and NMFS approves the seasonal PSC apportionments in Tables 16 and 17 to maximize harvest among gear types, fisheries, and seasons while minimizing bycatch of PSC.

TABLE 14—FINAL 2023 AND 2024 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON-TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS

PSC species and area and zone [1]	Total PSC	Non-trawl PSC	CDQ PSQ reserve [2]	Trawl PSC remaining after CDQ PSQ	Amendment 80 sector [3]	BSAI trawl limited access sector	BSAI PSC limits not allocated [3]
Halibut mortality (mt) BSAI	3,515	710	315	n/a	1,745	745	.....
Herring (mt) BSAI	3,444	n/a	n/a	n/a	n/a	n/a	.....
Red king crab (animals) Zone 1	32,000	n/a	3,424	28,576	14,282	8,739	5,555
C. opilio (animals) COBLZ	4,350,000	n/a	465,450	3,884,550	1,909,256	1,248,494	726,799
C. bairdi crab (animals) Zone 1	830,000	n/a	88,810	741,190	312,115	348,285	80,790
C. bairdi crab (animals) Zone 2	2,520,000	n/a	269,640	2,250,360	532,660	1,053,394	664,306

[1] Refer to § 679.2 for definitions of areas and zones.
[2] The PSQ reserve for crab species is 10.7 percent of each crab PSC limit.
[3] The Amendment 80 Program reduced apportionment of the trawl PSC limits for crab below the total PSC limit. These reductions are not apportioned to other gear types or sectors.

TABLE 15—FINAL 2023 AND 2024 HERRING AND RED KING CRAB SAVINGS SUBAREA PROHIBITED SPECIES CATCH ALLOWANCES FOR ALL TRAWL SECTORS

Fishery categories	Herring (mt) BSAI	Red king crab (animals) zone 1
Yellowfin sole	200	n/a
Rock sole/flathead sole/Alaska plaice/other flatfish [1]	99	n/a
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	10	n/a
Rockfish	10	n/a
Pacific cod	18	n/a
Midwater trawl pollock	3,066	n/a
Pollock/Atka mackerel/other species [2] [3]	41	n/a
2023 Red king crab savings subarea non-pelagic trawl gear [4]	n/a	0
2024 Red king crab savings subarea non-pelagic trawl gear [5]	n/a	8,000
Total trawl PSC	3,444	32,000

Note: Species allowances may not total precisely due to rounding.
[1] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[2] Pollock other than midwater trawl pollock, Atka mackerel, and "other species" fishery category.
[3] "Other species" for PSC monitoring includes skates, sharks, and octopuses.
[4] Section 679.21(e)(3)(ii)(B) establishes criteria under which an annual red king crab bycatch limit must be specified for the Red King Crab Savings Subarea (RKCSS) if the State has established a GHL fishery for red king crab in the Bristol Bay area in the previous year. Based on the final 2022 NMFS trawl survey data for the Bristol Bay red king crab stock, the State of Alaska closed the Bristol Bay red king crab fishery for the 2022/2023 crab season. NMFS and the Council will not specify the red king crab bycatch limit for the RKCSS in 2023, and pursuant to § 679.21(e)(3)(ii)(B)(*1*) directed fishing for groundfish is prohibited for vessels using non-pelagic trawl gear in the RKCSS for 2023.
[5] If the Bristol Bay red king crab fishery remains closed in the 2023/2024 crab season, NMFS and the Council will not specify the red king crab bycatch limit for the RKCSS in 2024. If the Bristol Bay red king crab fishery is open in the 2023/2024 crab season, NMFS, after consultation with the Council, will specify an annual red king crab bycatch limit for the RKCSS, which is limited by regulation to up to 25 percent of the red king crab PSC allowance and based on the need to optimize groundfish harvest relative to red king crab bycatch (§ 679.21(e)(3)(ii)(B)(*2*)).

TABLE 16—FINAL 2023 AND 2024 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR

BSAI trawl limited access fisheries	Prohibited species and area and zone [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Yellowfin sole	265	7,700	1,192,179	293,234	1,005,879
Rock sole/flathead sole/Alaska plaice/other flatfish [2]	.....	.....	.....	.....	.....
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	.....	.....	.....	.....	.....
Rockfish April 15–December 31	5	.....	1,006	.....	849
Pacific cod	300	975	50,281	50,816	42,424
Pollock/Atka mackerel/other species [3]	175	65	5,028	4,235	4,243

TABLE 16—FINAL 2023 AND 2024 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR—Continued

BSAI trawl limited access fisheries	Prohibited species and area and zone [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Total BSAI trawl limited access PSC	745	8,739	1,248,494	348,285	1,053,394

Note: Seasonal or sector allowances may not total precisely due to rounding.
[1] Refer to § 679.2 for definitions of areas and zones.
[2] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[3] "Other species" for PSC monitoring includes skates, sharks, and octopuses.

TABLE 17—FINAL 2023 AND 2024 HALIBUT PROHIBITED SPECIES BYCATCH ALLOWANCES FOR NON-TRAWL FISHERIES

Non-trawl fisheries	Seasons	Halibut mortality (mt) BSAI		
		Catcher/ processor	Catcher vessel	All non-trawl
Pacific cod	Total Pacific cod	648	13	661.
	January 1–June 10	388	9	n/a.
	June 10–August 15	162	2	n/a.
	August 15–December 31	98	2	n/a.
Non-Pacific cod non-trawl-Total	May 1–December 31	n/a	n/a	49.
Groundfish pot and jig	n/a	n/a	n/a	Exempt.
Sablefish fixed gear	n/a	n/a	n/a	Exempt.
Total for all non-trawl PSC	n/a	n/a	n/a	710.

Note: Seasonal or sector allowances may not total precisely due to rounding.

Estimates of Halibut Biomass and Stock Condition

The IPHC annually assesses the abundance and potential yield of the Pacific halibut stock using all available data from the commercial and sport fisheries, other removals, and scientific surveys. Additional information on the Pacific halibut stock assessment may be found in the IPHC's 2022 Pacific halibut stock assessment (December 2022), available on the IPHC website at *www.iphc.int.* The IPHC considered the 2022 Pacific halibut stock assessment at its January 2023 annual meeting when it set the 2023 commercial halibut fishery catch limits.

Halibut Discard Mortality Rates (DMRs)

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, DMRs, and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. Halibut incidental catch rates are based on observed estimates of halibut incidental catch in the groundfish fishery. DMRs are estimates of the proportion of incidentally caught halibut that do not survive after being returned to the sea. The cumulative halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. DMRs are estimated using the best scientific information available in conjunction with the annual BSAI stock assessment process. The DMR methodology and findings are included as an appendix to the annual BSAI groundfish SAFE report.

In 2016, the DMR estimation methodology underwent revisions per the Council's directive. An interagency halibut working group (IPHC, Council, and NMFS staff) developed improved estimation methods that have undergone review by the Plan Team, SSC, and the Council. A summary of the revised methodology is included in the BSAI proposed 2017 and 2018 harvest specifications (81 FR 87863, December 6, 2016), and the comprehensive discussion of the working group's statistical methodology is available from the Council (see **ADDRESSES**). The DMR working group's revised methodology is intended to improve estimation accuracy, transparency, and transferability used for calculating DMRs. The working group will continue to consider improvements to the methodology used to calculate halibut mortality, including potential changes to the reference period (the period of data used for calculating the DMRs). The methodology continues to ensure that NMFS is using DMRs that accurately reflect halibut mortality, which will inform the sectors of their estimated halibut mortality and allow sectors to respond with methods that could reduce mortality and, eventually, the DMR for that sector.

At the December 2022 meeting, the SSC, AP, and the Council concurred with the revised DMR estimation methodology, and NMFS adopts for 2023 and 2024 the DMRs calculated under the revised methodology, which uses an updated 2-year reference period. The final 2023 and 2024 DMRs in this rule are unchanged from the DMRs in the proposed 2023 and 2024 harvest specifications (87 FR 76435, December 14, 2022). Table 18 lists these final 2023 and 2024 DMRs.

TABLE 18—2023 AND 2024 PACIFIC HALIBUT DISCARD MORTALITY RATES (DMR) FOR THE BSAI

Gear	Sector	Halibut discard mortality rate (percent)
Pelagic trawl	All	100
Non-pelagic trawl	Mothership and catcher/processor	85
Non-pelagic trawl	Catcher vessel	62
Hook-and-line	Catcher/processor	9
Hook-and-line	Catcher vessel	9
Pot	All	26

Directed Fishing Closures

In accordance with § 679.20(d)(1)(i), the Regional Administrator may establish a DFA for a species or species group if the Regional Administrator determines that any allocation or apportionment of a target species has been or will be reached. If the Regional Administrator establishes a DFA, and that allowance is or will be reached before the end of the fishing year, NMFS will prohibit directed fishing for that species or species group in the specified subarea, regulatory area, or district (see § 679.20(d)(1)(iii)). Similarly, pursuant to § 679.21(b)(4) and (e)(7), if the Regional Administrator determines that a fishery category's bycatch allowance of halibut, red king crab, *C. bairdi* crab, or *C. opilio* crab for a specified area has been reached, the Regional Administrator will prohibit directed fishing for each species or species group in that fishery category in the area specified by regulation for the remainder of the season or fishing year.

Based on historical catch patterns and anticipated fishing activity, the Regional Administrator has determined that the groundfish allocation amounts in Table 19 will be necessary as incidental catch to support other anticipated groundfish fisheries for the 2023 and 2024 fishing years. Consequently, in accordance with § 679.20(d)(1)(i), the Regional Administrator establishes the DFA for the species and species groups in Table 19 as zero mt. Therefore, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing for these sectors and species or species groups in the specified areas effective at 1200 hours, A.l.t., March 10, 2023, through 2400 hours, A.l.t., December 31, 2024. Also, for the BSAI trawl limited access sector, bycatch allowances of halibut, red king crab, *C. bairdi* crab, and *C. opilio* crab listed in Table 19 are insufficient to support directed fisheries. Therefore, in accordance with § 679.21(b)(4)(i) and (e)(7), NMFS is prohibiting directed fishing for these sectors, species, and fishery categories in the specified areas effective at 1200 hours, A.l.t., March 10, 2023, through 2400 hours, A.l.t., December 31, 2024.

TABLE 19—2023 AND 2024 DIRECTED FISHING CLOSURES [1]

[Groundfish and halibut amounts are in metric tons. Crab amounts are in number of animals.]

Area	Sector	Species	2023 Incidental catch allowance	2024 Incidental catch allowance
Bogoslof District	All	Pollock	300	300
Aleutian Islands subarea	All	Greenland Turbot	529	449
Aleutian Islands subarea	All	ICA pollock	2,500	2,500
		"Other rockfish" [2]	380	380
Aleutian Islands subarea	Trawl non-CDQ	Sablefish	1,794	2,081
Eastern Aleutian District/Bering Sea.	Non-amendment 80, CDQ, and BSAI trawl limited access.	ICA Atka mackerel	800	800
Eastern Aleutian District/Bering Sea.	All	Blackspotted/Rougheye rockfish	305	330
Eastern Aleutian District	Non-amendment 80, CDQ, and BSAI trawl limited access.	ICA Pacific ocean perch	100	100
Central Aleutian District	Non-amendment 80, CDQ, and BSAI trawl limited access.	ICA Atka mackerel	75	75
		ICA Pacific ocean perch	60	60
Western Aleutian District	Non-amendment 80, CDQ and BSAI trawl limited access.	ICA Atka mackerel	20	20
		ICA Pacific ocean perch	10	10
Western and Central Aleutian Districts.	All	Blackspotted/Rougheye rockfish	141	155
Bering Sea subarea	Trawl non-CDQ	Sablefish	3,398	4,112
Bering Sea subarea	All	Pacific ocean perch	10,118	9,945
		"Other rockfish" [2]	748	748
		ICA pollock	50,000	50,000
Bering Sea and Aleutian Islands		Shortraker rockfish	451	451
		Skates	23,325	23,738
		Sharks	213	213
		Octopuses	340	340
	Hook-and-line and pot gear	ICA Pacific cod	500	500
	All	ICA flathead sole	3,000	3,000
		ICA rock sole	6,000	6,000
	All	ICA yellowfin sole	4,000	4,000
	BSAI trawl limited access	Rock sole/flathead sole/other flatfish—halibut mortality, red king crab Zone 1, *C. opilio* COBLZ, *C. bairdi* Zone 1 and 2.		
		Turbot/arrowtooth/Kamchatka/sablefish—halibut mortality, red king crab Zone 1, *C. opilio* COBLZ, *C. bairdi* Zone 1 and 2.		
		Rockfish—red king crab Zone 1		

[1] Maximum retainable amounts may be found in Table 11 to 50 CFR part 679.

[2] "Other rockfish" includes all *Sebastes* and *Sebastolobus* species except for dark rockfish, Pacific ocean perch, northern rockfish, blackspotted/rougheye rockfish, and shortraker rockfish.

Closures implemented under the final 2022 and 2023 BSAI harvest specifications for groundfish (87 FR 11626, March 2, 2022) remain effective under authority of these final 2023 and 2024 harvest specifications and until the date specified in those closure notifications. Closures are posted at the following website under the Alaska filter for Management Area: *https://www.fisheries.noaa.gov/rules-and-announcements/bulletins.* While these closures are in effect, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a fishing trip. These closures to directed fishing are in addition to closures and prohibitions found at 50 CFR part 679.

Listed AFA Catcher/Processor Sideboard Limits

Pursuant to § 679.64(a), the Regional Administrator is responsible for restricting the ability of listed AFA CPs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA fishery and from fishery cooperatives in the directed pollock fishery. These restrictions are set out as sideboard limits on catch. On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CPs from directed fishing for all groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and Table 54 to 50 CFR part 679). Section 679.64(a)(1)(v) exempts AFA CPs from a yellowfin sole sideboard limit because the final 2023 and 2024 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Section 679.64(a)(2) and Tables 40 and 41 to 50 CFR part 679 establish a formula for calculating PSC sideboard limits for halibut and crab caught by listed AFA CPs. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). PSC species listed in Table 20 that are caught by listed AFA CPs participating in any groundfish fishery other than pollock will accrue against the final 2023 and 2024 PSC sideboard limits for the listed AFA CPs. Section 679.21(b)(4)(iii), (e)(3)(v), and (e)(7) authorizes NMFS to close directed fishing for groundfish other than pollock for listed AFA CPs once a final 2023 or 2024 PSC sideboard limit listed in Table 20 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by listed AFA CPs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories, according to § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 20—FINAL 2023 AND 2024 BSAI AFA LISTED CATCHER/PROCESSOR PROHIBITED SPECIES SIDEBOARD LIMITS

PSC species and area [1]	Ratio of PSC catch to total PSC	2023 and 2024 PSC available to trawl vessels after subtraction of PSQ [2]	2023 and 2024 AFA catcher/processor sideboard limit [2]
Halibut mortality BSAI	n/a	n/a	286
Red king crab Zone 1	0.0070	28,576	200
C. opilio (COBLZ)	0.1530	3,884,550	594,336
C. bairdi Zone 1	0.1400	741,190	103,767
C. bairdi Zone 2	0.0500	2,250,360	112,518

[1] Refer to § 679.2 for definitions of areas.
[2] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.

AFA Catcher Vessel Sideboard Limits

Pursuant to § 679.64(b), the Regional Administrator is responsible for restricting the ability of AFA CVs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA fishery and from fishery cooperatives in the pollock directed fishery. On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CVs from directed fishing for a majority of the groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and Table 55 to 50 CFR part 679). Section 679.64(b)(6) exempts AFA CVs from a yellowfin sole sideboard limit because the final 2023 and 2024 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt. The remainder of the sideboard limits for non-exempt AFA CVs are in Table 21.

Section 679.64(b)(3) and (b)(4) and Tables 40 and 41 to 50 CFR part 679 establish formulas for setting AFA CV groundfish and halibut and crab PSC sideboard limits for the BSAI. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). Table 21 lists the final 2023 and 2024 AFA CV groundfish sideboard limits.

TABLE 21—FINAL 2023 AND 2024 BSAI PACIFIC COD SIDEBOARD LIMITS FOR AMERICAN FISHERIES ACT CATCHER VESSELS (CVS)

[Amounts are in metric tons]

Fishery by area/gear/season	Ratio of 1997 AFA CV catch to 1997 TAC	2023 initial TAC	2023 AFA catcher vessel sideboard limits	2024 initial TAC	2024 AFA catcher vessel sideboard limits
BSAI	n/a	n/a	n/a	n/a	n/a
Trawl gear CV	n/a	n/a	n/a	n/a	n/a
Jan 20–Apr 1	0.8609	19,837	17,078	19,237	16,561
Apr 1–Jun 10	0.8609	2,949	2,539	2,859	2,461
Jun 10–Nov 1	0.8609	4,021	3,462	3,899	3,357

Note: Section 679.64(b)(6) exempts AFA catcher vessels from a yellowfin sole sideboard limit because the 2023 and 2024 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Halibut and crab PSC limits listed in Table 22 that are caught by AFA CVs participating in any groundfish fishery other than pollock will accrue against the 2023 and 2024 PSC sideboard limits for the AFA CVs. Section 679.21, at (b)(4)(iii), (e)(3)(v), and (e)(7), authorizes NMFS to close directed fishing for groundfish other than pollock for AFA CVs once a final 2023 or 2024 PSC sideboard limit listed in Table 22 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by AFA CVs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories under § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 22—FINAL 2023 AND 2024 AMERICAN FISHERIES ACT CATCHER VESSEL PROHIBITED SPECIES CATCH SIDEBOARD LIMITS FOR THE BSAI [1]

PSC species and area [1]	Target fishery category [2]	AFA catcher vessel PSC sideboard limit ratio	2023 and 2024 PSC limit after subtraction of PSQ reserves [3]	2023 and 2024 AFA catcher vessel PSC sideboard limit [3]
Halibut	Pacific cod trawl	n/a	n/a	887
	Pacific cod hook-and-line or pot	n/a	n/a	2
	Yellowfin sole total	n/a	n/a	101
	Rock sole/flathead sole/Alaska plaice/other flatfish [4].	n/a	n/a	228
	Greenland turbot/arrowtooth/Kamchatka/sablefish.	n/a	n/a	.....
	Rockfish	n/a	n/a	2
	Pollock/Atka mackerel/other species [5]	n/a	n/a	5
Red king crab Zone 1	n/a	0.2990	28,576	8,544
C. opilio COBLZ	n/a	0.1680	3,884,550	652,604
C. bairdi Zone 1	n/a	0.3300	741,190	244,593
C. bairdi Zone 2	n/a	0.1860	2,250,360	418,567

[1] Refer to § 679.2 for definitions of areas.
[2] Target trawl fishery categories are defined at § 679.21(b)(1)(ii)(B) and (e)(3)(iv).
[3] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.
[4] ''Other flatfish'' for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[5] ''Other species'' for PSC monitoring includes skates, sharks, and octopuses.

Response to Comments

Comment 1: The proposed groundfish harvest specifications do not consider the current status of Chinook and chum salmon.

Response: NMFS and the Council considered the status of Chinook and chum, and the harvest specifications reflect adjustments based on promulgated regulations. NMFS and the Council have taken comprehensive action through Amendments 91 and 110 to the FMP and implementing regulations to reduce salmon bycatch in the pollock trawl fishery because of the potential for negative impacts on salmon stocks. Existing measures have reduced salmon bycatch in the pollock fishery compared with what they would have been without the measures. Regulations set limits on how many Chinook salmon can be caught in a year in the pollock fishery, and those regulations require bycatch caps to be calculated and implemented in the annual harvest specifications. NMFS annually allocates portions of either 33,318, 45,000, 47,591, or 60,000 Chinook salmon PSC limits among the AFA sectors, depending on past bycatch performance, on whether Chinook salmon bycatch incentive plan agreements (IPAs) are formed and approved by NMFS, and on whether NMFS determines it is a low Chinook salmon abundance year. NMFS will determine that it is a low Chinook salmon abundance year when abundance of Chinook salmon in western Alaska is less than or equal to 250,000 Chinook salmon. The State of Alaska provides NMFS with an estimate of Chinook salmon abundance using the 3-System Index for western Alaska based on the Kuskokwim, Unalakleet,

and Upper Yukon aggregate stock grouping. For 2023, NMFS determined it was a low abundance year based on the State of Alaska's 3-System Index. In accordance with the regulations at § 679.21(f), NMFS has specified a Chinook salmon PSC limit of 45,000 Chinook salmon, and a Chinook salmon bycatch performance standard of 33,318.

Regulations also set limits on Chinook PSC for the AI pollock fishery and non-Chinook salmon PSC for vessels using trawl gear from August 15 through October 14 in the Catcher Vessel Operational Area (CVOA) (§ 679.21(f)(14) and (g)(2)). These are static limits that are announced in the groundfish harvest specifications.

NMFS acknowledges the western Alaska salmon crisis and the impact it is having on culture and food security throughout western Alaska. Science indicates climate change as the primary driver of poor salmon returns in western Alaska. The Council and NMFS are committed to continued improvements in bycatch management with a goal of minimizing bycatch at all levels of salmon and pollock abundance. NMFS and the Council are currently engaged in a comprehensive process to evaluate existing measures and develop alternatives that may be necessary to further reduce chum salmon bycatch. More information on this process can be found at *https://www.npfmc.org/fisheries-issues/bycatch/salmon-bycatch/.* However, the Chinook and chum salmon limits and the conditions that affect the limits are set in regulations, and changes to those regulations are outside of the scope of the annual harvest specification process. NMFS believes that changes to bycatch management of all PSC, including Chinook and chum, are best accomplished through the Council process to recommend FMP amendments and regulations that NMFS would implement if consistent with the Magnuson-Stevens Act, the FMP, and other applicable law.

Comment 2: The pollock allocations do not allow for the sustainable harvest of Western Alaska Chinook and chum salmon. NMFS must address how the pollock allocations will not have significant impacts on salmon bycatch.

Response: NMFS recognizes the significant importance of salmon for Alaska Native people and tribes in terms of food security, cultural practices, and a way of life. NMFS manages salmon bycatch in the pollock fishery through a variety of tools, which include Chinook salmon PSC limits, monitoring, and IPAs to address Chinook and chum bycatch. These tools apply at all levels of pollock allocations.

Please see the response to Comment 1 for a description of the Chinook salmon PSC limits that constrain Chinook and non-Chinook bycatch in the pollock fishery.

To support bycatch management goals, NOAA Fisheries (NMFS) has a comprehensive monitoring program to collect data on salmon bycatch. This information is used to estimate how many Chinook and chum salmon are caught as bycatch from trawl vessels, where those fish came from, and whether a potential violation of law occurred. To support catch and bycatch data collection needs on catcher/processors and motherships, two fishery observers on board each vessel ensure that every haul is monitored. All catcher vessels in the Bering Sea pollock fisheries are required to carry an observer or an electronic monitoring system on every trip. All salmon bycatch must be delivered to the shoreside processor and every pollock delivery is monitored in entirety for salmon bycatch to enable a full accounting.

Under Amendments 91 and 110 to the FMP and Federal regulation at 50 CFR 679.21 (Prohibited Species Bycatch Management), the pollock fleet participates in an industry-developed contractual arrangement, called an incentive plan agreement (IPA). An IPA establishes an incentive program to minimize bycatch at all levels of Chinook and chum salmon abundance. To ensure participants develop effective IPAs, participants provide the Council and NMFS an annual report that describes the efforts each IPA is taking to accomplish the intent of the program that each vessel actively avoids Chinook and chum salmon at all times while fishing for pollock and, collectively, that bycatch is minimized in each year. The IPA system is designed to be flexible and responsive, and can be tailored by each sector to fit its operational needs. The IPAs impose rewards for avoiding Chinook salmon bycatch or penalties for failure to avoid Chinook and chum salmon bycatch at the vessel level. Since implementation, all the participants in the pollock fishery are currently participating in IPAs.

In 2022, 8,324 Chinook salmon were incidentally caught in the BSAI groundfish fisheries with 6,337 Chinook salmon out of the total attributed to the BSAI pollock directed fisheries. Historic Chinook catches are posted on the NMFS website: *https://www.fisheries.noaa.gov/sites/default/files/akro/chinook_salmon_mortality2022.html.*

In 2022, 245,269 chum salmon were incidentally caught in the BSAI groundfish fisheries with 242,375 chum salmon out of the total attributed to the BSAI pollock directed fisheries. Historic non-Chinook salmon catches are posted on the NMFS website: *https://www.fisheries.noaa.gov/sites/default/files/akro/chum_salmon_mortality2022.html.*

NMFS has adult equivalence estimates of the Chinook salmon that would have returned to river systems had they not been caught as bycatch in the BS pollock fishery. The most recent estimates of salmon bycatch, which use the best available science, show that estimated bycatch in the pollock fishery is less than 3 percent of the Chinook salmon returns and less than 1 percent of the chum salmon returns in Western Alaska. Since 2011, the peak estimate of Chinook bycatch is less than 2 percent of the Western Alaska returns, as stated in the most recent Eastern BS pollock SAFE Report.

Reducing the pollock TAC likely would have an extremely small effect on salmon returns, and therefore on in-river harvest opportunities, because of the low level of bycatch of salmon in the pollock fishery. The management measure recommended by the Council and implemented in regulation by NMFS (the Chinook bycatch limit) sets an overall limit on the number of Chinook salmon taken as bycatch, as well as a performance standard (which is less than the overall limit to incentivize reducing bycatch). The pollock fleet is constrained by the limit of Chinook salmon set in regulation, regardless of the size of the pollock harvest. Sectors are prohibited from continuing to fish if their PSC limit has been exceeded. Further, if the sector exceeds its performance standard in 3 of 7 years, that sector becomes constrained by the performance standard in future years (meaning, the sector has a lower PSC limit).

There is not currently an overall limit on the number of chum salmon taken as bycatch. Instead, chum salmon bycatch is managed via IPAs in the pollock fishing sectors, which provide incentives for vessels to avoid salmon bycatch under any condition of pollock or salmon abundance. Consistent annual genetic data show the majority of chum bycatch is of Asian hatchery origin, and thus does not affect returns to western Alaska rivers. Nevertheless, the Council is considering additional measures to minimize chum salmon bycatch in the future.

While 2022 was a relatively low TAC for pollock, because of low recruitments in previous years, the pollock TAC has been relatively consistent since new Chinook bycatch measures were

implemented in 2011, and new Chinook and chum bycatch measures were implemented in 2016 (§ 679.21(f)): *https://media.fisheries.noaa.gov/2022-03/bsai-harvest-specs-1986-present.pdf.*

While pollock catches have been consistent from year to year since 2011, Chinook and chum bycatch has varied independently of stable pollock TACs.

Comment 3: National Standard 1 states that NMFS and the Council must consider social, economic, and ecological factors when setting OY, maximum sustainable yield (MSY), and TAC. Under National Standard 1, there must be a reduction in pollock TAC to provide increased escapement and subsistence opportunities for Western Alaska villages.

Response: The Council and NMFS have considered social, economic, and ecological factors in setting OY, MSY, and TAC, and the pollock TAC specified in these final groundfish harvest specification is consistent with the FMP and National Standards. National Standard 1 states that conservation and management measures must prevent overfishing while achieving on a continuing basis the OY from the fishery (16 U.S.C. 1851(a)(1)). The Council and NMFS have previously determined and set the MSY and OY for the groundfish fishery of the BSAI management area, with OY set in the FMP and in regulation as a range of 1.4 million to 2.0 million mt (§ 679.20(a)(1)). It is therefore outside the scope of the harvest specifications process to consider adjustments to the OY and MSY.

In accordance with National Standard 1 and regulations, the SSC recommends for each species and species group an OFL and an ABC. The catch limits (TAC) cannot exceed the ABC (50 CFR 600.310(f)(4)). TAC must be set equal to or less than ABC, and ABC must be set equal to or less than OFL (§ 600.310(f)(3) and (4)). NMFS specifies TAC after consultation with the Council, and annual determinations of TAC are based on review of both the biological condition of the specific species or species group and socioeconomic conditions (§ 679.20(a)(2)–(3)). Here, for 2023, the Council has recommended a BS pollock TAC of 1,300,000 mt, which is 32 percent below the ABC of 1,910,000 mt. The ABC is 62 percent less than the OFL of 3,381,000 mt. This specification of OFL, ABC, and TAC is consistent with National Standard 1 guidelines. The 2023 BS pollock TAC is also 18,000 mt below the past 10-year mean of BS pollock TACs. NMFS concurs with the Council's recommended specification of the 2023 BS pollock TAC. This TAC is based on consideration of the biological condition of the pollock stock, as reviewed in the SAFE pollock chapter; the status of the ecosystem, as reviewed in the Bering Sea ecosystem status report (ESR); and socioeconomic considerations, as reviewed in the SAFE pollock chapter and Economic Status Report. NMFS also concurs with the Council that the specification of all TACs at the upper bound of 2.0 million mt is consistent with National Standard 1, as well as the FMP and the harvest strategy selected as the preferred alternative in the EIS (see response to Comment 5). The specification of all TACs at 2.0 million mt is consistent with historical pollock allocations in years of high pollock abundance. In addition, as explained in response to Comment 2, reducing the pollock TAC would not meaningfully increase salmon returns to Western Alaska given the small percentages of salmon stocks taken as bycatch in the pollock fishery and the constraining PSC limit that applies at any level of pollock harvest.

Comment 4: Even though pollock catches salmon as bycatch, pollock TAC increased while salmon returns have decreased.

Response: Pollock TACs in the BS are cyclical depending on pollock recruitment. While the 2022 TAC was lower than normal due to decreased pollock abundance, the recommended 2023 TACs are similar to the historical average TACs, and thus larger than the 2022 TAC. The best scientific information available does not suggest that a reduction in the pollock TAC would measurably increase salmon escapement to western Alaska (see response to Comment 2). While salmon bycatch in the pollock fishery may be a contributing factor in the decline of salmon, NMFS expects the numbers of the ocean bycatch that would have returned to western Alaska would be relatively small due to ocean mortality and the large number of other river systems contributing to the total Chinook or chum salmon bycatch. For Chinook salmon, the bycatch expected to have returned to western Alaska rivers is less than 3 percent of coastal western Alaska run size in recent years, and less than 2 percent since 2011. For 2021, the estimate of bycaught salmon that would have returned to Western Alaska is 8,610 fish with an estimate of 7,705 fish from 2011 through 2020. For chum salmon, the chum salmon bycatch expected to have returned to western Alaska rivers is less than 1 percent of the coastal western Alaska run size in recent years. For 2021, the number of bycaught salmon expected to return to Western Alaska is estimated to be 51,510 fish with an estimate of 49,290 fish annually from 2011 through 2020.

Comment 5: Explain how OY is reached considering the decreased salmon returns.

Response: The Council recommended and NMFS set the OY as a range of 1.4 to 2 million mt. This OY is set forth in the FMP and in regulation, and is based on the sum of all TACs. NMFS has therefore determined that, in any given year, setting the TACs to fall within that range provides the greatest overall benefit to the Nation, particularly with respect to food production and recreational opportunities and taking into account the protection of marine ecosystems and relevant economic, social, or ecological factors (§ 600.310(e)(3)). Here, NMFS concurs with the Council's recommendation that TACs fall within the upper bound (2 million mt). Setting TACs to meet the upper bound of the OY range of 2.0 million mt, while also recognizing that total TACs represent a 32 percent reduction below total ABCs, balances relevant National Standard 1 considerations. Setting TACs at the higher bound of the OY will provide the greatest benefit for the Nation based on the benefits of maintaining viable groundfish fisheries and contributions to regional and local economies. That total groundfish removals are 32 percent below total ABC recognizes the benefits that flow from that reduction, such as protections afforded to marine ecosystems, forage for ecosystem components, and other ecological factors (§ 600.310(e)(3)(iii)(A)–(B)).

NMFS has determined that further reductions in TAC are not necessary. As stated in the responses to previous comments, the recommended TACs are not expected to significantly affect the returns of Chinook and chum salmon to Western Alaska. Moreover, the pollock fleet is constrained by a PSC limit that applies regardless of fishing effort and the catch limits (TAC) for pollock. Therefore, for the 2023 and 2024 groundfish harvest specifications, the OY is reached by adopting TACs whose sum is within this range while not exceeding the ABCs developed through the SAFE reports and recommended by the Council and SSC.

Comment 6: The harvest specifications use an outdated EIS.

Response: Groundfish harvests are managed subject to annual limits on the retained and discarded amounts of each species and species group. The ''harvest strategy'' is the method used to calculate the annual limits, referred to as ''harvest specifications,'' and the process of establishing them is referred to as the ''specifications process.'' NMFS

prepared the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS) to analyze alternatives to implement the FMP's harvest strategy and specifications process, which outlines the method and process used to determine the annual harvest specifications for the federally managed groundfish fisheries in the GOA and BSAI management areas. NMFS also must specify PSC allowances in the annual harvest specifications.

A harvest strategy is needed for the management of the groundfish fisheries and the conservation of marine resources, as required by the Magnuson-Stevens Act and as described in the management policy, goals, and objectives in the FMP (16 U.S.C. 1853(a)(15)). The purpose of the harvest strategy is to provide for orderly and controlled commercial fishing for groundfish; promote sustainable incomes to the fishing, fish processing, and support industries; support sustainable fishing communities; and provide sustainable flows of fish products to consumers. The harvest strategy balances groundfish harvest in the fishing year with ecosystem needs (such as non-target fish stocks, marine mammals, seabirds, and habitat).

NMFS concluded that the harvest strategy provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant. NMFS has not changed the harvest strategy or specifications process from what was analyzed in the Final EIS.

Each year the harvest strategy uses the best scientific information available in the annual SAFE reports to derive the annual harvest specifications, which include TACs and PSC limits. The SAFE reports are available (see **ADDRESSES**). Through this process, each year, the Council's Groundfish Plan Teams use updated stock assessments to calculate biomass, OFLs, and ABCs for each species and species group for specified management areas. The OFLs and ABCs are published with the harvest specifications, and provide the foundation for the Council and NMFS to develop the TACs. The OFLs and ABCs reflect fishery science, applied in light of the requirements of the FMPs. The Council bases its TAC recommendations on those of its AP, which are consistent with the SSC's OFL and ABC recommendations (meaning, the TAC recommendations cannot exceed the SSC's ABC and OFL recommendations).

The Final EIS evaluates the consequences of alternative harvest strategies on ecosystem components and on the ecosystem as a whole. The Final EIS evaluates the alternatives for their effects within the action area. The environmental consequences of each alternative were considered for target species, non-specified species, forage species, prohibited species, marine mammals, seabirds, Essential Fish Habitat, ecosystem relationships, the economy, and environmental justice. These considerations were evaluated based on the conditions as they existed at the time the EIS was developed. However, each year since 2007 relevant changes (new information, changed circumstances, potential changes to the action) are considered with the primary purpose of evaluating the need to supplement the Final EIS.

NEPA implementing regulations at 40 CFR 1502.9(d) instruct agencies to prepare supplements to either draft or final environmental impact statements if: (i) The agency makes substantial changes to the proposed action that are relevant to environmental concerns; or (ii) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts.

Not every change requires a supplemental EIS (SEIS); only those changes that cause significantly different effects from those already studied require supplementary consideration. The Supreme Court directs that ''an agency need not supplement an EIS every time new information comes to light after the EIS is finalized. To require otherwise would render agency decision making intractable.'' *Marsh* v. *Oregon Nat. Res. Council,* 490 U.S. 360, 373 (1989). On the other hand, if a major Federal action remains to occur, and if new information indicates that the remaining action will affect the quality of the human environment in a significant manner or to a significant extent not already considered, an SEIS must be prepared. Ultimately, an agency is required ''to take a 'hard look' at the new information to assess whether supplementation might be necessary.'' *Norton* v. *S. Utah Wilderness All.,* 542 U.S. 55, 72–73 (2004).

NEPA implementing regulations at § 1502.9(d)(4) stipulate that an agency may find that changes to the proposed action are not substantial or new circumstances or information relevant to environmental concerns are not significant and therefore do not require a supplement to an EIS. As stipulated under 40 CFR 1507.3 and NOAA Administrative Order 216–6A, NOAA's NEPA procedures are found in the Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities (Companion Manual). Appendix C of the Companion Manual authorizes the use of a Supplementary Information Report (SIR) to document a review of new information or circumstances that differ from that described in an existing NEPA document to determine the sufficiency of the existing analysis and subsequent decision. The SIR contains the rationale for and decision regarding whether new information or circumstances or changes to the action are significant and thus whether an SEIS is required. The SIR also looks at reasonably foreseeable future actions to gauge whether a future action, individually or cumulatively, could cause a substantial change in the action or represent significant new circumstances or new information that would require an SEIS in the future.

A SIR for the Final EIS is prepared each year to document the evaluation and decision whether an SEIS is necessary to implement the annual groundfish harvest specifications. The SIR analyzes the information contained in the most recent SAFE reports and all information available to NMFS and the Council to determine whether an SEIS should be prepared. The SAFE reports represent the best scientific information available for the harvest specifications. Included in the SAFE reports are the groundfish stock assessments, the website for the ESR for the SAFE reports, and the website for the Economic Status Report for the SAFE reports. To date, no annual SIR to the EIS has concluded that an SEIS is necessary. This is largely due to the flexibility built into the process and the alternatives evaluated (particularly the preferred harvest strategy as implemented) in the Final EIS. That inherent flexibility allows for the implementation of annual harvest specifications that reflect new information and changing circumstances.

The preferred harvest strategy analyzed in the Final EIS anticipated that changes in information would be used each year in setting the annual harvest specification since the process is flexible to adjust to new information on stock abundance and environmental and socioeconomic factors (like climate change). Similarly, the FMP contemplates ongoing consideration of relevant factors through the development of SAFE reports (Section

3.2.2.2 of the FMP). The use of new information from the SAFE reports allows the Council and NMFS to respond to changes in stock condition and environmental and socioeconomic factors in the BSAI and to adjust the harvest specifications as necessary, which is consistent with the preferred harvest strategy from the Final EIS and the FMP and which is consistent with National Standard 2 of the Magnuson-Stevens Act to use the best scientific information available (16 U.S.C. 1851(a)(2)).

Separate from the Final EIS, the Council and NMFS prepared the Alaska Groundfish Programmatic Supplemental Environmental Impact Statement (PSEIS). The Council is currently considering approaches, such as a programmatic EIS, to provide a comprehensive analysis of the impacts of the Federal groundfish fisheries on the human environment, with a view towards creating more climate-resilient Federal fisheries. This has involved an ongoing discussion of the 2004 PSEIS. The scope of, and changes from, the 2004 PSEIS are outside the scope of this action.

Comment 7: The process of setting OFLs and ABCs does not account for the viability of all species in the BSAI.

Response: The process of setting OFLs and ABCs is an expansive process that accounts for the best scientific information available on target species as well as ecosystem considerations like non-target species. The SSC and the Council recommend OFLs and ABCs to prevent overfishing as mandated in National Standard 1 of the MSA. The OFLs and ABCs apply only to targets of directed fisheries. However, through ecosystem considerations in both the ESR for the SAFE and the NEPA process, impacts on a wider range of species is considered during the harvest specification process. In addition, the setting of OFLs and ABCs informs the setting of TACs since the TAC cannot exceed the ABC for each species and species group. The sum of all TACs must fall within the OY range. The OY is based on the management objectives of the FMP, as well as relevant social, economic, and ecological factors (§ 600.310(e)(3)). Ecological factors include ecosystem component species, forage fish stocks, other fisheries, predator-prey or competitive interactions, marine mammals, threatened or endangered species, and birds. The FMP addresses how the OY for the BSAI groundfish fishery reflects ecological factors (see, for example, Section 3.2.2.2 and Section 4.6 of the FMP). In this way, the annual harvest specifications process results in annual OFLs, ABCs, and TACs that, although set for target species only, are based on consideration of ecosystem and ecological factors, including species other than target species. When possible, stock assessment models include information on ecosystem and environmental effects to improve the interpretation of historical information and the precision of forecasts. NMFS is committed to supporting science and research to move us toward effective ecosystem-based management. Developing additional tools and approaches for incorporating ecosystem factors will allow us to deal with the impacts of climate and other environmental change on our marine species.

Comment 8: The Secretary of Commerce must minimize bycatch under National Standard 9.

Response: National Standard 9 directs that conservation and management measures shall, to the extent practicable, minimize bycatch. The Council and NMFS develop and implement FMP amendments and regulations for new bycatch reduction measures. The harvest specifications set PSC, or bycatch, limits for salmon and crab based on pre-existing frameworks set out in regulation; each of these earlier actions establishing a PSC, or bycatch, limit considered and balanced all the National Standards, including the direction to minimize bycatch to the extent practicable. Specifying bycatch levels in the annual harvest specifications consistent with the existing PSC regulations is therefore consistent with National Standard 9.

Comment 9: Under National Standards 4 and 8, the Secretary must allocate fishery resources fairly among fishermen and adopt conservation and management measures that account for the importance of fishery resources to communities. In the proposed harvest specifications decision, the Secretary has not provided a sufficient consideration of the ecological, economic, and social factors required under National Standards 4 and 8.

Response: National Standard 4 states that conservation and management measures shall not discriminate between residents of different states (16 U.S.C. 1851(a)(4)). The harvest specifications do not discriminate or differentiate among residents of different states. The harvest specifications further implement annual allocations of fishing privileges among fishermen. These allocations were implemented in regulation through previous rulemakings that considered and balanced all the National Standards, including National Standard 4. These harvest specifications are therefore consistent with National Standard 4.

National Standard 8 states that conservation and management measures shall take into account the importance of fishery resources to fishing communities by utilizing economic and social data in order to: (A) provide for the sustained participation of such communities, and (B) to the extent practicable, minimize adverse economic impacts on such communities (16 U.S.C. 1851(a)(8)). This is addressed in the harvest specifications process at § 679.20(a)(3)(ii). TACs are set at or below ABCs to prevent overfishing. TACs are set within the OY range, a range that the Council and NMFS determined will provide the greatest overall benefit to the National with respect to food production and in consideration of relevant economic and social factors. The FMP's definition of OY recognized: ''1. The OY range is not likely to have any significant detrimental impact on the industry. On the contrary, specification of OY as a constant range helps to create a stable management environment in which the industry can plan its activities consistently, with an expectation that each year's total groundfish catch will be at least 1.4 million mt. 2. The OY range encompasses the annual catch levels taken in the period immediately prior to its implementation, during which the fishery operated profitably.'' TACs within this range will ensure the sustained participation of fishing communities. As addressed in the response to Comment 5, NMFS concurs with the Council's recommendation that TACs fall within the upper bound (2 million mt) and that further reductions are not necessary.

In addition, many of the conservation and management measures effectuated through the annual harvest specifications were implemented in prior rulemakings that are outside of the scope of the current specification process to change. These would include allocations to communities, use caps, and limits on bycatch, which are set in regulation. These regulations created allocations, caps, and limits that are addressed in the specification process and specified in the annual specifications. The prior rulemakings on these conservation and management measures considered and balanced all the National Standards, including National Standard 8. The final harvest specifications are therefore consistent with National Standard 8.

Comment 10: The current NEPA analysis supporting the groundfish harvest specifications does not consider climate change.

Response: The Final EIS analyzed alternatives for an implementing framework for the BSAI and GOA harvest strategy and evaluated the potential effects of those alternatives on the human environment (see response to Comment 6). The EIS examined existing physical and oceanographic conditions in the BSAI and GOA, and addressed regime shifts, warming and loss of sea ice, and acidification (Section 3.5 of the Final EIS). Moreover, the framework process for the preferred harvest strategy under the Final EIS allows for the effects of climate change to be considered in the annual process for setting the harvest specifications.

The annual ESR is part of the SAFE reports that the Council and its Plan Teams, SSC, and AP annually review prior to the review of the stock assessments and advancing recommendations of the annual OFLs, ABCs, and TACs. Contributions to the ESR are developed by scientists and fishery managers at NOAA, other U.S. Federal and State agencies, academic institutions, tribes, nonprofits, and other sources. Ongoing research incorporated into the ESR has increased our understanding of the interactions among ecosystem components, including how they are impacted by changing environmental conditions related to climate change. The ESR, published each December, informs annual harvest recommendations. The purpose of the ESR is to provide the Council, scientific community, and the public with annual information about ecosystem status and trends. Information from the report is integrated into the annual harvest recommendations through inclusion in stock assessment-specific risk tables and is considered during the annual groundfish and crab Plan Team meetings and Council meetings. The target audience for this report is the SSC to provide context for setting the annual OFLs and ABCs, and for the Council's final TAC recommendations for groundfish and crab. This report includes physical oceanography, biological data, and socio-ecological dimensions, primarily collected from Alaska Fisheries Science Center (AFSC) surveys with collaboration from a range of government and non-government partners. There are many examples of climate change considerations presented in the ESR, such as reevaluating the importance of survey distribution of stocks like Pacific cod and pollock based on water temperature.

In some instances, the Plan Teams and SSC have recommended ABC reductions based on climate change considerations. Stock assessments use a stock-assessment specific risk table that is applied by evaluating the severity of four types of considerations that could be used to support a scientific recommendation to reduce the ABC from the maximum permissible ABC. The four considerations are assessment-related, population dynamics, environmental/ecosystem, and fishery performance. As one environmental/ecosystem consideration, scientists noted for one stock that patterns in distribution, growth, and size were associated with warmer ocean conditions and the cumulative effects from a series of recent warm years. That consideration warranted an increased level concern under the risk table. These risk tables are now prepared as part of the stock assessment process for groundfish stocks and help inform the setting of ABC (which in turn informs the setting of TAC).

Finally, the FMP indicated that the ongoing consideration of ecological factors like climate change would be addressed annually in the SAFE reports (Section 3.2.2.2 of the FMP), as is currently the case with the both individual stock assessments and the ESRs. As a result, the annual harvest specifications process, which implements the preferred harvest strategy under the EIS, allows for the consideration of the best scientific information available on climate change (16 U.S.C. 1851(a)(2)).

Comment 11: TACs should be set using ecosystem management.

Response: Ecosystem considerations inform the specification of TACs in a variety of ways. As detailed in the SAFE reports, ecosystem considerations are incorporated into the harvest specifications process. Information about the ecosystem is included in the groundfish stock assessments used to determine the OFL and ABC, which in turn inform the TAC, for all target species and species groups in the BSAI. When possible, stock assessment models include information on ecosystem and environmental effects to improve the interpretation of historical information and the precision of forecasts. As explained in the response to Comment 10, in some cases, ABCs have been reduced from the assessment model based on the ecosystem considerations presented in the risk tables. And, as explained in the response to Comment 10, the annual ESRs further allow for the consideration of ecosystem factors during the process to specify annual OFLs and ABCs for target species and species groups.

NMFS is required to prevent overfishing, so no TAC may exceed the ABC as determined by the population dynamics of any particular stock. However, in the BSAI, the TACs are not set equal to ABCs. Both the FMP and regulations limit the sum of the TACs from the ecosystem at 2 million mt, so the TACs are further reduced to meet this limit in years of high ABCs. This reduction in TACs to 2 million mt reduces fishery removals and therefore impacts on the ecosystem. For the 2023 harvest specifications, the total TAC has been reduced by 1.2 million mt to ensure the sum of all TACs is within the OY range.

OY is the amount of fish that will provide the greatest overall benefit to the Nation, taking into account the protection of marine ecosystems and relevant economic, social, or ecological factors (§ 600.310(e)(3)). OY is based on the management objectives of the FMP, as well as relevant ecological factors like ecosystem component species, forage fish stocks, other fisheries, predator-prey or competitive interactions, marine mammals, threatened or endangered species, and birds. The FMP addresses how the OY for BSAI groundfish fishery reflects ecosystem and ecological factors (see, for example, Section 3.2.2.2 and Section 4.6 of the FMP). The FMP further indicated that the ongoing consideration of ecosystem and ecological factors relevant to OY would be addressed annually in the SAFE reports (Section 3.2.2.2 of the FMP). Consistent with the FMP, the sum of the TACs must be within the OY range, and all TACs are informed by both individual stock assessments (including the risk tables) and the ESR for the SAFE report, which are updated annually to address ecosystem factors.

As a result, the harvest specification process, including the specification of TACs, considers best scientific information available on ecosystem factors. As noted above, NMFS is committed to supporting science and research to move us toward effective ecosystem-based management and developing additional tools and approaches for incorporating ecosystem factors.

Comment 12: Current evaluations fail to account for the true environmental cost of the pollock TAC for trawl fishing.

Response: Ecosystem considerations, as well as the impact on communities and incidentally caught species, are considered annually in the ESR to the SAFE report as well as individual stock SAFE reports. The chapter on pollock includes discussions on the ecosystem as well as sections titled ''Ecosystem effects on the EBS pollock stock'' and ''EBS pollock fishery effects on the ecosystem.'' The ecosystem is also evaluated in the Final EIS, which in

turn is annually evaluated in the SIR. Additionally, the environmental impacts of the pollock fishery have been analyzed in a number of subsequent NEPA documents, including the Environmental Impact Statement for Amendment 91 to the FMP and the Environmental Assessment for Amendment 110 to the FMP.

NMFS is required to achieve an OY on a continuing basis. The FMP and implementing regulations dictate an OY of 1.4 to 2 million mt. In the BSAI, it is currently not possible to reach that range without the use of trawl gear.

Comment 13: The floor for *Chionoecedes opilio* (*C. opilio* or snow crab) PSC should be removed. Crab PSC limits should be changed because they fail to account for limitations identified by scientists, such as recruitment failures or other bottlenecks in aspects of the current environmental conditions that limit the reproductive ability of the stock and because they do not provide groundfish trawl sectors incentive to move away from areas of high bycatch.

Response: The PSC limit for *C. opilio* crab was developed and implemented by Amendments 40 and 57 to the FMP. The PSC limit for *C. opilio* crab is set forth in regulation, which directs NMFS to specify annually the limit based on total abundance of *C. opilio* crab as indicated by the NMFS annual bottom trawl survey. The regulations direct that the limit will be 0.1133 percent of total abundance, minus 150,000 *C. opilio* crabs, unless a minimum or maximum limit specified in regulation applies (§ 679.21(e)(1)(iii)). In these specifications, NMFS has calculated and specified the PSC limit for *C. opilio* crab based on total abundance from the NMFS annual bottom trawl survey. In addition, in these groundfish harvest specifications, the Council recommends and NMFS adopts amounts of crab PSC limits between trawl fishery categories as outlined in § 679.21(e)(3). These harvest specifications set forth the *C. opilio* crab PSC limits consistent with existing regulations. Any changes to the floor for the *C. opilio* crab PSC limit is beyond the scope of these annual groundfish harvest specifications. Changes to the *C. opilio* crab PSC limit would need to be reviewed and analyzed through the Council process in an action separate from the groundfish harvest specifications. To note, the Council is working on developing potential conservation and management actions to improve crab bycatch management and further reduce fishing impacts on Bristol Bay red king crab and Eastern Bering Sea *C. opilio* crab.

Similarly, PSC limits for *Chionoecetes bairdi* (*C. bairdi* or Tanner crab) are set forth in regulations that dictate specific *C. bairdi* crab PSC limits based on total abundance of crabs as indicated by the NMFS annual bottom trawl survey (§ 679.21(e)(1)(ii)). In accordance with these regulations, NMFS calculated the applicable *C. bairdi* crab PSC limit based on total abundance and specified that PSC limit in these groundfish harvest specifications. Any changes to the regulations on crab PSC limits are beyond the scope of these annual groundfish harvest specifications. Changes to the *C. bairdi* crab PSC limit would need to be reviewed and analyzed through the Council process in an action separate from the groundfish harvest specifications. Separate actions for crab PSC will rely upon the crab SAFE documents, which do consider the impact of trawl bycatch on crab abundance.

Comment 14: Catch levels of Pacific cod should be increased to reduce predation on crab.

Response: As discussed above, the most recent scientific information available from the 2022 stock assessments is used to set the 2023 and 2024 OFLs, ABCs, and TACs for all groundfish species, including BSAI Pacific cod. The Council recommended, and NMFS approved, the 2023 and 2024 BSAI Pacific cod TACs at the maximum amounts available after setting aside the amounts needed to support the State's GHL fisheries. This recommendation is made to ensure that catch in Federal and State waters does not exceed the ABC. Further increasing Pacific cod TACs could lead to overfishing, and would violate the MSA and National Standard 1 guidelines that direct that catch (TAC) may not exceed fishing level recommendations (OFL and ABC) (16 U.S.C. 1852(h)(6)) and that conservation and management measures shall prevent overfishing (16 U.S.C. 1851(a)(1)).

Comment 15: NMFS should take a precautionary approach to fisheries management decisions, like the harvest specifications decision.

Response: NMFS takes a precautionary approach to fisheries management in setting the annual harvest specifications. NMFS's primary objective for fisheries management decisions including the harvest specifications process is the conservation and management of fish resources. Currently, no Alaska groundfish species are known to be experiencing overfishing.

Stock assessments provide important scientific information necessary for the conservation and management of fish stocks. The stock assessments use a six-tiered system that accommodates different levels of reliable information available to fishery scientists for determining OFLs and ABCs. Fishery scientists use the equations from an appropriate tier to determine when a stock is overfished according to the reliability of information available. The six-tiered system accomplishes three basic functions: (1) It compensates for uncertainty in estimating fishing mortality rates at a level of MSY by establishing fishing mortality rates more conservatively as biological parameters become more imprecise (less reliable); (2) it relates fishing mortality rates directly to biomass for stocks below target abundance levels, so that fishing mortality rates fall to zero should a stock become critically depleted; and (3) it maintains a buffer between the ABC and the OFL to further minimize the possibility of catches jeopardizing a stock's long term productivity. Also, stock assessments use a risk table that is applied by evaluating the severity of four types of considerations that could be used to support a scientific recommendation to reduce the ABC from the maximum permissible ABC. The four considerations are assessment-related, population dynamics, environmental/ecosystem, and fishery performance.

For the harvest specifications, the stock assessments that produce the OFLs and ABCs have several levels of review. The AFSC internally reviews the stock assessment, and then the Plan Team and SSC reviews the stock assessment, which incorporates public comment during public meetings. Also several stock assessments are peer reviewed using the Center for Independent Experts, which is important in ensuring the incorporation of the best scientific information available for the conservation and management measures to ensure sustainability of our Nation's living marine resources.

The annual determinations of TAC for each species or species group may be based on a review of the biological condition of groundfish stocks. SAFE documents prepared annually for the Council and NMFS provide information on historical catch trends; updated estimates of the MSY of the groundfish complex and its component species groups; assessments of the stock condition of each target species; assessments of the multispecies and ecosystem impacts of harvesting the groundfish complex at current levels, the assessed condition of stocks, including consideration of rebuilding depressed stocks; and alternative harvesting strategies and related effects on the component species group. The

SAFE reports also include the socioeconomic considerations that are consistent with the goals of the FMPs for the groundfish, including the need to promote efficiency in the utilization of fishery resources and minimize costs; the need to manage for the optimum marketable size of a species; the impact of groundfish harvests on prohibited species and the domestic target fisheries that utilize these species; the desire to enhance depleted stocks; the seasonal access to the groundfish fishery by domestic fishing vessels; the commercial importance of a fishery to local communities; the importance of a fishery to subsistence users; and the need to promote utilization of certain species.

Comment 16: NMFS should take a hard look at minimizing impacts to the seafloor on essential crab habitat, and minimizing unobserved mortality due to fishing gear interactions. There should be a hard look at all fishing gear groups on how to best balance this approach.

Response: NMFS implements the groundfish harvest specifications process in accordance with the regulations set forth at 50 CFR part 679, which include regulations to close areas to fishing to protect habitat, modify gear to minimize impacts to the seafloor, specify allocations to specific gear and operational sectors, and limit PSC for vessels using specific gear. These final specifications are developed in accordance with these regulations. Any changes to the regulations to address gear impacts are beyond the scope of the groundfish harvest specifications process. Separate from the groundfish harvest specifications process, the Council has recently taken action to look at changes to reduce crab bycatch mortality and how to estimate unobserved mortality for crab stocks.

Comment 17: Industry has inequitable access to the Council and NMFS.

Response: These final harvest specifications were developed through a public process that began with Plan Team review at September and November meetings, which are open to the public. The SSC and Council review occurred at their October and December meetings. These meetings are also open to the public. The public can comment in writing and/or orally at these meetings. Comments can be given in-person or virtually for online participants. Finally, NMFS published the proposed harvest specifications in the **Federal Register** for 30 days of public comment (87 FR 76435, December 14, 2022). Included in both the proposed and final specifications is a person of contact and their telephone number. Additionally, information to guide the public through the Council and regulatory processes are available on the Council web page (*https://www.npfmc.org/*) and NMFS Alaska Region web page (see **ADDRESSES**).

NMFS is cognizant that the Council and regulatory processes may be unfamiliar to newer participants and interested individuals. NMFS will endeavor to improve accessibility and outreach to the public to help individuals and interested participants better understand Council and regulatory processes and the opportunities and methods for public input.

Classification

NMFS is issuing this final rule pursuant to section 305(d) of the Magnuson-Stevens Act. Through previous actions, the FMP and regulations are designed to authorize NMFS to take this action. See 50 CFR part 679. The NMFS Assistant Administrator has determined that the final harvest specifications are consistent with the FMP and with the Magnuson-Stevens Act and other applicable laws.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Order 12866 because it only implements annual catch limits in the BSAI.

NMFS prepared an EIS for the Alaska groundfish harvest specifications and alternative harvest strategies (see **ADDRESSES**) and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the Record of Decision (ROD) for the Final EIS. In January-February 2023, NMFS prepared a Supplementary Information Report (SIR) for this action to provide a subsequent assessment of the action and to address the need to prepare a Supplemental EIS (SEIS) (40 CFR 1501.11(b); § 1502.9(d)(1)). Copies of the Final EIS, ROD, and annual SIRs for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental, social, and economic consequences of the groundfish harvest specifications and alternative harvest strategies on resources in the action area. Based on the analysis in the Final EIS, NMFS concluded that the preferred alternative (Alternative 2) provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information. The preferred alternative is a harvest strategy in which TACs are set at a level within the range of ABCs recommended by the Council's SSC; the sum of the TACs must achieve the OY specified in the FMP. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant.

The latest annual SIR evaluated the need to prepare an SEIS for the 2023 and 2024 groundfish harvest specifications. An SEIS must be prepared if: (1) the agency makes substantial changes in the proposed action that are relevant to environmental concerns; or (2) significant new circumstances or information exist relevant to environmental concerns and bearing on the proposed action or its impacts (§ 1502.9(d)(1)). After reviewing the information contained in the SIR and SAFE report, the Regional Administrator has determined that: (1) approval of the 2023 and 2024 harvest specifications, which were set according to the preferred harvest strategy in the Final EIS, does not constitute a substantial change in the action; and (2) there are no significant new circumstances or information relevant to environmental concerns and bearing on the action or its impacts that are not addressed through the annual process of using the preferred harvest strategy to set the 2023 and 2024 harvest specifications. Additionally, the 2023 and 2024 harvest specifications will result in environmental, social, and economic impacts within the scope of those analyzed and disclosed in the Final EIS. Therefore, an SEIS is not necessary to implement the 2023 and 2024 harvest specifications.

A final regulatory flexibility analysis (FRFA) was prepared. Section 604 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 604) requires that, when an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law, to publish a general notice of proposed rulemaking, the agency shall prepare a FRFA. The following constitutes the FRFA prepared for these final 2023 and 2024 harvest specifications.

Section 604 of the RFA describes the required contents of a FRFA: (1) a statement of the need for, and objectives of, the rule; (2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement

of any change made to the proposed rule in the final rule as a result of the comments; (4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

A description of this action, its purpose, and its legal basis are included at the beginning of the preamble to this final rule and are not repeated here.

NMFS published the proposed rule on December 14, 2022 (87 FR 76435). NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA) to accompany the proposed action, and included the IRFA in the proposed rule. The comment period closed on January 13, 2023. No comments were received on the IRFA or on the economic impacts of the rule more generally. The Chief Counsel for Advocacy of the Small Business Administration did not file any comments on the proposed rule.

The entities directly regulated by this action are those that harvest groundfish in the exclusive economic zone of the BSAI and in parallel fisheries within State waters. These include entities operating CVs and CPs within the action area and entities receiving direct allocations of groundfish.

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.

Using the most recent data available (2021), the estimated number of directly regulated small entities includes approximately 146 CVs, 6 CPs, and 6 CDQ groups. Some of these vessels are members of AFA inshore pollock cooperatives, Gulf of Alaska rockfish cooperatives, or BSAI Crab Rationalization Program cooperatives, and, since under the RFA, the aggregate gross receipts of all participating members of the cooperative must meet the ''under $11 million'' threshold, the cooperatives are considered to be large entities within the meaning of the RFA. Thus, the estimate of 146 CVs may be an overstatement of the number of small entities. Average gross revenues in 2021 were $700,000 for small hook-and-line vessels, $1.1 million for small pot vessels, and $2.1 million for small trawl vessels. Average gross revenues for CP entities are confidential.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

This action implements the final 2023 and 2024 harvest specifications, apportionments, and prohibited species catch limits for the groundfish fishery of the BSAI. This action is necessary to establish harvest limits for groundfish during the 2023 and 2024 fishing years and is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act. The establishment of the final harvest specifications is governed by the Council's harvest strategy for the catch of groundfish in the BSAI. The harvest strategy was previously selected from among five alternatives. Under this preferred alternative harvest strategy, TACs are set within the range of ABCs recommended by the SSC; the sum of the TACs must achieve the OY specified in the FMP; and while the specific TAC numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant. This final action implements the preferred alternative harvest strategy previously chosen by the Council to set TACs that fall within the range of ABCs recommended through the Council harvest specifications process and as recommended by the Council. This is the method for determining TACs that has been used in the past.

The final 2023 and 2024 TACs associated with the preferred harvest strategy are those recommended by the Council in December 2022. OFLs and ABCs for each species and species group were based on recommendations prepared by the Council's Plan Team, and reviewed by the Council's SSC. The Council's TAC recommendations are consistent with the SSC's OFL and ABC recommendations, and the sum of all TACs remains within the OY for the BSAI consistent with § 679.20(a)(1)(i)(A). Because setting all TACs equal to ABCs would cause the sum of TACs to exceed an OY of 2 million mt, TACs for some species and species groups are lower than the ABCs recommended by the Plan Team and the SSC.

The final 2023 and 2024 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods to calculate stock biomass. The final 2023 and 2024 TACs are based on the best available biological and socioeconomic information. The final 2023 and 2024 OFLs, ABCs, and TACs are consistent with the biological condition of groundfish stocks as described in the 2022 SAFE report, which is the most recent, completed SAFE report. Accounting for the most recent biological information to set the final OFLs, ABCs, and TACs is consistent with the objectives for this action, as well as National Standard 2 of the Magnuson-Stevens Act (16 U.S.C. 1851(a)(2)) that actions shall be based on the best scientific information available.

Under this action, the ABCs reflect harvest amounts that are less than the specified overfishing levels. The TACs are within the range of ABCs recommended by the SSC and do not exceed the biological limits recommended by the SSC (the ABCs and OFLs). For some species and species groups in the BSAI, the Council recommended, and NMFS sets, TACs equal to ABCs, which is intended to maximize harvest opportunities in the BSAI. However, NMFS cannot set TACs for all species in the BSAI equal to their ABCs due to the constraining OY limit of 2 million mt. For this reason, some final TACs are less than the final ABCs. These specific reductions were reviewed and recommended by the Council's AP, and then reviewed and adopted by the Council as the Council's recommended final 2023 and 2024 TACs.

Based on the best available scientific data, and in consideration of the Council's objectives for this action, there are no significant alternatives that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the final rule on small entities. This action is economically beneficial to entities operating in the BSAI, including small entities. The action specifies TACs for

commercially-valuable species in the BSAI and allows for the continued prosecution of the fishery, thereby creating the opportunity for fishery revenue. After public process, during which the Council solicited input from stakeholders, the Council concluded that these final harvest specifications would best accomplish the stated objectives articulated in the preamble for this final rule and in applicable statutes, and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

Adverse impacts on marine mammals, or endangered or threatened species, resulting from fishing activities conducted under this rule are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Pursuant to 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries, NOAA, finds good cause to waive the 30-day delay in the date of effectiveness for this rule because delaying the effective date of this final rule is contrary to the public interest. The Plan Team review of the 2022 SAFE report occurred in November 2022, and based on the 2022 SAFE report the Council considered and recommended the final harvest specifications in December 2022. Accordingly, NMFS's review of the final 2023 and 2024 harvest specifications could not begin until after the December 2022 Council meeting, and after the public had time to comment on the proposed action.

For all fisheries not currently closed because the TACs established under the final 2022 and 2023 harvest specifications (87 FR 11626, March 2, 2022) were not reached, it is possible that they would be closed prior to the expiration of a 30-day delayed effectiveness period because their TACs could be reached within that period. If implemented immediately, this rule would allow these fisheries to continue fishing because some of the new TACs implemented by this rule are higher than the TACs under which they are currently fishing.

In addition, immediate effectiveness of this action is required to provide consistent management and conservation of fishery resources based on the best available scientific information. This is particularly pertinent for those species that have lower 2023 ABCs and TACs than those established in the 2022 and 2023 harvest specifications (87 FR 11626, March 2, 2022). If implemented immediately, this rule would ensure that NMFS can properly manage those fisheries for which this rule sets lower 2023 ABCs and TACs based on the most recent biological information on the condition of stocks.

Certain fisheries, such as those for pollock, are intensive, fast-paced fisheries. Other fisheries, such as those for sablefish, flatfish, rockfish, Atka mackerel, skates, sharks, and octopuses, are critical as directed fisheries and as incidental catch in other fisheries. U.S. fishing vessels have demonstrated the capacity to catch the TAC allocations in many of these fisheries. If the date of effectiveness of this final rule were to be delayed 30 days and if a TAC were to be reached during those 30 days, NMFS would be required to close directed fishing or prohibit retention for the applicable species. Any delay in allocating the final TACs in these fisheries would cause confusion to the industry and potential economic harm through unnecessary discards, thus undermining the intent of this rule. Waiving the 30-day delay allows NMFS to prevent economic loss to fishermen that could otherwise occur should the 2023 TACs (previously set under the 2022 and 2023 harvest specifications) be reached. Determining which fisheries may close is nearly impossible because these fisheries are affected by several factors that cannot be predicted in advance, including fishing effort, weather, movement of fishery stocks, and market price. Furthermore, the closure of one fishery has a cascading effect on other fisheries by freeing-up fishing vessels, allowing them to move from closed fisheries to open ones, increasing the fishing capacity in those open fisheries, and in turn causing them to close at an accelerated pace.

In fisheries subject to declining sideboard limits, a failure to implement the updated sideboard limits before initial season's end could deny the intended economic protection to the non-sideboard limited sectors. Conversely, in fisheries with increasing sideboard limits, economic benefit could be denied to the sideboard-limited sectors.

If these final harvest specifications are not effective by March 10, 2023, which is the start of the 2023 Pacific halibut season as specified by the IPHC, the fixed gear sablefish fishery will not begin concurrently with the Pacific halibut IFQ season. Delayed effectiveness of this action would result in confusion for sablefish harvesters and economic harm from the unnecessary discard of sablefish that are caught along with Pacific halibut, as both fixed gear sablefish and Pacific halibut are managed under the same IFQ program. Immediate effectiveness of these final 2023 and 2024 harvest specifications will allow the sablefish IFQ fishery to begin concurrently with the Pacific halibut IFQ season.

Finally, immediate effectiveness also would provide the fishing industry the earliest possible opportunity to plan and conduct its fishing operations with respect to new information about TAC limits. Therefore, NMFS finds good cause to waive the 30-day delay in the date of effectiveness for this rule under 5 U.S.C. 553(d)(3).

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The tables contained in this final rule are provided online and serve as the plain language guide to assist small entities in complying with this final rule as required by the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule's primary purpose is to announce the final 2023 and 2024 harvest specifications and prohibited species bycatch allowances for the groundfish fisheries of the BSAI. This action is necessary to establish harvest limits and associated management measures for groundfish during the 2023 and 2024 fishing years and is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act. This action directly affects all fishermen who participate in the BSAI fisheries. The specific amounts of OFL, ABC, TAC, and PSC amounts are provided in tables in this final rule to assist the reader. This final rule also contains plain language summaries of the underlying relevant regulations supporting the harvest specifications and the harvest of groundfish in the BSAI that the reader may find helpful.

Information to assist small entities in complying with this final rule is provided online. The OFL, ABC, TAC, and PSC tables are individually available online at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-groundfish-harvest-specifications.* Explanatory information on the relevant regulations supporting the harvest specifications is found in footnotes to the tables. Harvest specification changes are also available from the same online source, which includes applicable **Federal Register** notices, information bulletins, and other supporting materials. NMFS will announce closures of directed fishing in the **Federal Register** and information

bulletins released by the Alaska Region. Affected fishermen should keep themselves informed of such closures.

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: March 6, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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Proposed Rules

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

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2022–0143]

Draft Regulatory Guide: Criteria for Programmable Digital Devices in Safety-Related Systems of Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory guide (DG), DG–1374, ''Criteria for Programmable Digital Devices in Safety-Related Systems of Nuclear Power Plants.'' This DG is proposed Revision 4 of Regulatory Guide (RG) 1.152, ''Criteria for Use of Computers in Safety Systems of Nuclear Power Plants.'' DG–1374 describes an approach that is acceptable to the NRC staff to meet regulatory requirements for promoting high functional reliability, design quality, and a secure development and operational environment (SDOE) for the use of programmable digital devices (PDDs) in the safety-related systems of nuclear power generating stations.

DATES: Submit comments by April 10, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0143. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michael Eudy, Office of Nuclear Regulatory Research, telephone: 301–415–3104, email: *Michael.Eudy@nrc.gov* and Khoi Nguyen, Office of Nuclear Reactor Regulation, telephone: 301–415–6839, email: *Khoi.Nguyen@nrc.gov*. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0143 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0143.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov*. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0143 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The DG, entitled ''Criteria for Programmable Digital Devices in Safety-Related Systems of Nuclear Power Plants,'' is temporarily identified by its task number, DG–1374 (ADAMS Accession No. ML23012A242).

This revision (Revision 4) of the guide endorses the Institute of Electrical and Electronic Engineers (IEEE) Standard (Std) 7–4.3.2–2016, ''IEEE Standard Criteria for Programmable Digital Devices in Safety Systems of Nuclear

Power Generating Stations,'' with some exceptions and clarifications. Specifically, this revision removes the previous SDOE guidance from this guide and instead endorses, with clarifications, the SDOE criteria within IEEE Std 7–4.3.2–2016. This revision also includes additional guidance for fault detection and self-diagnostics, if used, in Digital Instrumentation and Control systems. In addition, this revision endorses Annex D of IEEE Std 7–4.3.2–2016 and clarifies the applicability of the control of access guidance for safety-related PDDs.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML22132A293). The staff developed a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Proposed Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Backfitting, Forward Fitting, and Issue Finality

If finalized, the NRC staff may use this DG as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this DG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in Section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,'' nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in MD 8.4. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: March 3, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–04805 Filed 3–9–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[NRC–2018–0296]

RIN 3150–AK32

Renewing Nuclear Power Plant Operating Licenses—Environmental Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; public meetings and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) plans to hold comment-gathering public meetings on a proposed rule to amend its environmental protection regulations by updating the Commission's 2013 findings on the environmental effect of renewing the operating license of a nuclear power plant. The purpose of the meetings is to provide information and receive public comments on the proposed changes to NRC regulations, draft Revision 2 to NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants'' (LR GEIS), and associated guidance.

DATES: The NRC plans to hold public meetings in March and April 2023 during the 60-day public comment period. See Section III, ''Request for Comments and Public Meetings,'' of this document for more information on the meetings.

ADDRESSES: Please refer to Docket ID NRC–2018–0296 when contacting the NRC about the availability of information regarding this public meeting. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0296. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov*. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov*. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Yanely Malave-Velez, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1519, email: *Yanely.Malave-Velez@nrc.gov*; Jennifer Davis, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–3835, email: *Jennifer.Davis@nrc.gov*; or Kevin Folk, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6944, email: *Kevin.Folk@nrc.gov*. All are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0296 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0296.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov*.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville,

Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2018–0296 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On March 3, 2023, the NRC published a proposed rule in the **Federal Register** for a 60-day public comment period (88 FR 13329). The NRC proposes to amend its environmental protection regulations by updating the Commission's 2013 findings on the environmental effect of renewing the operating license of a nuclear power plant in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' subpart A, ''National Environmental Policy Act—Regulations Implementing Section 102(2).'' Additionally, the NRC proposes to revise NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants'' (LR GEIS), which is intended to streamline the NRC's license renewal environmental review by documenting a systematic approach that the NRC uses to evaluate the environmental impacts of renewing the operating licenses of commercial nuclear power plants. The LR GEIS also provides the technical basis for Table B–1, in appendix B to subpart A of 10 CFR part 51, ''Environmental Effect of Renewing the Operating License of a Nuclear Power Plant.'' Among other things, these proposals will update 10 CFR part 51 and the LR GEIS to fully account for subsequent license renewal as well as initial license renewal. The NRC will solicit comments at each meeting for consideration in the development of the final rule, LR GEIS, and associated guidance.

III. Request for Comments and Public Meetings

The NRC staff plans to hold the following comment-gathering public meetings during the 60-day public comment period to present an overview of the proposed changes to the environmental protection regulations and the LR GEIS.

- March 16, 2023, at the Bethesda North Marriott Hotel & Conference Center; First Meeting: Open House from 1:30 p.m.–2 p.m. and Public Meeting from 2 p.m.–4 p.m. (local time).
- Second Meeting: Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- March 28, 2023, at the Marriott Chicago Naperville; 1801 N Naperville Boulevard, Naperville, IL 60563. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- March 30, 2023, at the Marriott Dallas/Ft. Worth Westlake; 1301 Solana Boulevard, Building 3, Westlake, Texas 76262. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- April 4, 2023, at the Alloy King of Prussia; 301 West DeKalb Pike, King of Prussia, Pennsylvania 19406. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- April 6, 2023, at the Courtyard by Marriott Atlanta Decatur Downtown/Emory; 130 Clairemont Avenue, Decatur, GA 30303. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).

Interested stakeholders also may attend by telephone or online webinar. The public meetings will be transcribed and will include a presentation of the contents of the draft LR GEIS and proposed rule; and an opportunity for government agencies, organizations, and individuals to provide comments. No oral comments on the draft LR GEIS or proposed rule will be accepted during the open house sessions. To be considered, oral comments must be presented during the transcribed portion of the public meeting. The NRC staff also will accept written comments at any time during the public meetings. Persons interested in presenting oral comments at any of the six public meetings are encouraged to pre-register. Information for the teleconference and online webinar will be available in the meeting notices, which can be accessed through the NRC's Public Meeting Schedule at *https://www.nrc.gov/pmns/mtg*.

Members of the public also may register to provide oral comments in-person at each meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register.

If special equipment or accommodations are needed to attend or present information at a public meeting, please contact Yanely Malave-Velez, telephone: 301–415–1519, email: *Yanely.Malave-Velez@nrc.gov,* no later than 10 days before the designated scheduled meeting to provide the NRC staff adequate notice to determine whether the request can be accommodated.

The NRC requests that comments that are not provided during the meeting be submitted as noted in Section I, ''Obtaining Information and Submitting Comments,'' of this document in writing by May 2, 2023.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No. 1 **Federal Register** citation
Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review, March 3, 2023	88 FR 13329
Draft Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants	
Draft NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,'' Volume 1, Revision 2.	ML23010A078
Draft NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,'' Volume 2, Revision 2.	ML23010A086
Draft Guidance Documents	
Draft NUREG–1555, Supplement 1, Revision 2, ''Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal''.	ML22165A070
Draft Regulatory Guide DG–4027, ''Preparation of Environmental Reports for Nuclear Power Plant License Renewal Applications'' (also referenced as Regulatory Guide (RG) 4.2, Supplement 1).	ML22165A072

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2018–0296. The Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. The following actions are needed to subscribe: (1) navigate to the docket folder NRC–2018–0296, (2) click the ''Subscribe'' link, and (3) enter an email address and click on the ''Subscribe'' link.

Dated: March 7, 2023.

For the Nuclear Regulatory Commission.

Patricia K. Holahan,

Director, Subsequent License Environmental Directorate, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–04982 Filed 3–9–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 14 and 1120

[Docket No. FDA–2013–N–0227]

Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. This meeting will be held to discuss and provide an opportunity for recommendations on the Requirements for Tobacco Product Manufacturing Practice (TPMP) proposed rule. The meeting will be open to the public.

DATES: The meeting will be held on May 18, 2023, from 9 a.m. to 2 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://fda.zoomgov.com/j/1600966352?pwd=bmRrRlp1MlUrdWVmR095KzN3eWV1UT09;* Passcode: Y=Sw4a. Answers to commonly asked questions including information regarding special accommodations due to disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA has established a docket for public comment (Docket No. FDA–2013–N–0227). Please note that late, untimely filed comments will not be considered by the committee. Either electronic or written comments on this public advisory committee meeting must be submitted by May 11, 2023, for consideration by the committee. The *https://www.regulations.gov* electronic filing system will accept comments on this public advisory committee meeting until 11:59 p.m. Eastern Time at the end of May 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before May 11, 2023, will be provided to the committee and become part of the docket. Comments received after May 11, 2023, and prior to September 6, 2023, will also become part of the docket, but will not be considered by the committee. In the event that the meeting is canceled, FDA will continue to evaluate any relevant information and consider any comments submitted to the docket for the TPSAC meeting, as appropriate. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule published elsewhere in this issue of the **Federal Register** by September 6, 2023.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0227 and ''Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments.''

Comments on this public advisory committee meeting (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., Eastern Time, 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 identify as confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA 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 the 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: Serina Hunter-Thomas, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 1–877–287–1373, *TPSAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 18, 2023, the committee will meet in open session to discuss and provide recommendations on the TPMP proposed rule (proposed 21 CFR part 1120), published elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm* and can be accessed by scrolling down to the appropriate advisory committee meeting link.

Procedure: On May 18, 2023, from 9 a.m. to 2 p.m. Eastern Time, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 11, 2023, will be provided to the committee. In the event that the meeting is canceled, FDA will continue to evaluate any relevant information and consider any comments submitted to the docket for the TPSAC meeting, as appropriate. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule by September 6, 2023.

Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10:30 a.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on May 3, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m., May 4, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at *TPSAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04593 Filed 3–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1120

[Docket No. FDA–2013–N–0227]

Proposed Requirements for Tobacco Product Manufacturing Practice; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public oral hearing entitled ''Proposed Requirements for Tobacco Product Manufacturing Practice.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to prescribe current good manufacturing practice (cGMP) or hazard analysis and critical control point methodology (HACCP) regulations related to the manufacture, preproduction design validation, packing, and storage of tobacco products to protect public health and ensure compliance with the FD&C Act. In accordance with this provision, FDA is proposing requirements for tobacco product manufacturing practice (TPMP) elsewhere in this issue of the **Federal Register**. The FD&C Act further requires FDA to afford an opportunity for an oral hearing on the proposed regulation. We are holding this public oral hearing to carry out this statutory mandate and obtain information and views on the proposed TPMP requirements.

DATES: The public oral hearing will be held virtually on April 12, 2023, from 9:30 a.m. to 5 p.m. Eastern Time. All written notices of participation must be received by March 31, 2023 (email written notices of participation to: *CTPoutreach@fda.hhs.gov*). Either electronic or written comments on this public hearing must be submitted by September 6, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule published elsewhere in this issue of the **Federal Register** by September 6, 2023.

ADDRESSES: This public oral hearing will be held via an online teleconferencing platform. Additional details, such as the time of the public oral hearing and registration information, will be posted at *https://www.fda.gov/tobacco-products.* The online web conference meeting link can be accessed at *https://www.fda.gov/tobacco-products* on the day of the meeting.

All written notices of participation must be received by March 31, 2023 (email to: *CTPoutreach@fda.hhs.gov*). 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 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2013–N–0227 for ''Proposed Requirements for Tobacco Product Manufacturing Practices; Notice of Public Hearing; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Necola Staples or Robert Schwartz, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPOutreach@fda.hhs.gov* or *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA issued a proposed regulation on TPMP requirements (TPMP proposed rule). As described in the TPMP proposed rule, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) authorizes FDA to establish regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to cGMP or HACCP methodology. The TPMP proposed rule (proposed 21 CFR part 1120), if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products. These requirements, if finalized, will help protect the public health by ensuring that tobacco products are manufactured in facilities that meet basic requirements for manufacturing, packing, and storing tobacco products and are in compliance with chapter IX of the FD&C Act (21 U.S.C. 387 through 387u).

Section 906(e)(1)(B)(ii) of the FD&C Act requires FDA, before issuing a final TPMP regulation, to provide the public the opportunity for an oral hearing. To satisfy this requirement, FDA is holding this public oral hearing pursuant to part 15 (21 CFR part 15) to provide the opportunity for the public to present information and views on the proposed requirements.

II. Notice of Hearing Under Part 15

To satisfy the statutory requirement under section 906(e)(1)(B)(ii) of the FD&C Act, FDA will hold a public oral hearing consistent with part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA panelists, including subject matter experts from the Center for Tobacco Products. As provided in § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as provided in § 15.30(b) (see also *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

III. Topics for Discussion at the Public Oral Hearing

FDA is interested in the public's views, information, and any supporting data on the TPMP proposed rule, including the following topics:

- The proposed scope of the regulation to cover finished and bulk tobacco product manufacturers, including specification developers.
- Potential changes to the scope of the regulation, such as expanding the scope to cover manufacturers of all regulated tobacco products, including all components or parts, or limiting the scope to cover only manufacturers of certain products.
- FDA's proposed ''umbrella'' approach with flexible requirements to all affected entities as opposed to applying only specific or additional requirements for certain types of tobacco products.
- Product specifications in the Master Manufacturing Record (MMR). The proposed approach for the MMR would include any requirement established by the manufacturer as well as, at a minimum, certain specifications related to product content, design, and any applicable product standards.
- Design and development activities needed to control the risks associated with finished and bulk tobacco product and its production processes, packing, and storage. The proposed risk management process would include the risk treatment requirements intended to help prevent the manufacture and distribution of nonconforming and/or contaminated tobacco product.
- The proposed effective date—2 years for manufacturers (other than small tobacco product manufacturers) and a total of 6 years for small tobacco product manufacturers—for complying with any TPMP regulations.

IV. Participating in the Public Oral Hearing

Registration: To register to attend the free public oral hearing, please visit the following website: *https://www.fda.gov/tobacco-products.* Registration information will be posted soon. Live closed captioning will be provided during the public oral hearing. Additional information on requests for special accommodations due to a disability will be provided during registration.

Written Notice of Participation: During online registration you may indicate if you wish to present information and views at the hearing (oral statements without slides). FDA will do its best to accommodate requests to make public presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants ahead of the hearing. All written notices of participation must be received by March 31, 2023, 11:59 p.m. Eastern Time (email to: *CTPoutreach@fda.hhs.gov*). No commercial or promotional material will be permitted to be presented or distributed at the public oral hearing.

Transcripts: Please be advised that as soon as a transcript of the public oral hearing is available, it will be accessible at *https://www.regulations.gov.* Once available, the transcript may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/tobacco-products.*

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04592 Filed 3–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 13

[NPS–AKRO–35327; PPAKAKROZ5, PPMPRLE1Y.L00000]

RIN 1024–AE70

Alaska; Hunting and Trapping in National Preserves—Extension of Public Comment Period

AGENCY: National Park Service, Interior.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The National Park Service extends the public comment period for a proposed rule that would amend regulations for sport hunting and trapping in national preserves in Alaska.

Extending the comment period will allow more time for the public to review the proposal and submit comments.

DATES: The comment period for the proposed rule published on January 9, 2023 (88 FR 1176), is extended. Comments must be received by 11:59 p.m. EST on March 27, 2023.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024–AE70, by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or hand deliver to:* National Park Service, Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501. *Comments delivered on external electronic storage devices (flash drives, compact discs, etc.) will not be accepted.*
- *Instructions:* Comments will not be accepted by fax, email, or in any way other than those specified above. Comments delivered on external electronic storage devices (flash drives, compact discs, etc.) will not be accepted. All submissions received must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN (1024–AE70) for this rulemaking. Comments received will be posted without change to *www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *www.regulations.gov* and search for ''1024–AE70.''

FOR FURTHER INFORMATION CONTACT: Sarah Creachbaum, Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501; phone (907) 644–3510; email: *AKR_Regulations@nps.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: On January 9, 2023, the National Park Service (NPS) published in the **Federal Register** (88 FR 1176) a proposed rule that would amend regulations for sport hunting and trapping in national preserves in Alaska. The proposed rule would prohibit certain harvest practices, including bear baiting; prohibit predator control or predator reduction on national preserves; and clarify the regulatory definition of trapping. The public comment period for this proposal is scheduled to close on Friday, March 10, 2023. In order to give the public additional time to review and comment on the proposal, the NPS is extending the public comment period until Monday, March 27, 2023. Comments previously submitted on the proposed rule need not be resubmitted, as they will be fully considered in preparing the final rule.

Shannon Estenoz,

Assistant Secretary, for Fish and Wildlife and Parks.

[FR Doc. 2023–04981 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 230306–0067]

RIN 0648–BM00

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 54

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Amendment 54 to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (Gulf) (Amendment 54), as prepared by the Gulf of Mexico Fishery Management Council (Council). This proposed rule and Amendment 54 would revise Gulf greater amberjack sector allocations and catch limits. The purposes of this proposed rule and Amendment 54 are to end overfishing of Gulf greater amberjack and to update catch limits to be consistent with the best scientific information available.

DATES: Written comments must be received on or before April 10, 2023.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2023–0007,'' by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2023–0007'', in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Kelli O'Donnell, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of Amendment 54, which includes an environmental assessment, a fishery impact statement, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review, may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/amendment-54-modifications-greater-amberjack-catch-limits-sector-allocation-and-rebuilding.*

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, telephone: 727–824–5305, or email: *Kelli.ODonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery, which includes greater amberjack, under the FMP. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

All weights in this proposed rule are in round weight unless otherwise noted.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

Greater amberjack in the Gulf exclusive economic zone (EEZ) are managed as a single stock with

commercial and recreational annual catch limits (ACLs) and annual catch targets (ACTs)(quotas). The allocation of the stock ACL between the commercial and recreational sectors is 27 percent commercial and 73 percent recreational and was implemented through Amendment 30A to the FMP in 2008 (73 FR 38139, July 3, 2008). In Amendment 30A, the Council initially decided to establish sector allocations based on the long-term average landings from the recreational and commercial sectors from 1981 through 2004. However, during amendment development, the Council noted that the early years of the time series were primarily recreational landings (84 percent of landings from 1981–1987) while the most recent years in the allocation time series (2001–2004) had increasing landings by the commercial sector (32 percent of landings from 2001–2004). Ultimately, the Council agreed to an allocation that reassigned 2 percent of the commercial allocation to the recreational sector and established the current sector allocation.

Greater amberjack has been under a rebuilding plan since 2003. This rebuilding plan was implemented with Secretarial Amendment 2 and was expected to rebuild the stock by 2010 (68 FR 39898, July 3, 2003). In 2006, the Southeast Data, Assessment, and Review (SEDAR) 9 assessment showed that the greater amberjack stock was not recovering as previously projected. The stock continued to be overfished and was experiencing overfishing. The Council developed Amendment 30A to end overfishing and rebuild the stock by 2010, consistent with the time frame of the original rebuilding plan. In 2010, the SEDAR 9 Update was completed and indicated that the stock remained overfished and was continuing to experience overfishing. In response, the Council developed Amendment 35 to the FMP (77 FR 67574, December 13, 2012). The management measures implemented in Amendment 35 were expected to end overfishing; however, it could not be determined if the stock would meet its rebuilding schedule until a new benchmark assessment was completed. In 2014, the SEDAR 33 benchmark stock assessment was completed and showed that greater amberjack remained overfished, was experiencing overfishing as of 2012, and did not meet the rebuilding time established in Secretarial Amendment 2. In 2015, the Council developed a framework action that further reduced the sector ACLs and ACTs in an effort to end overfishing and rebuild the stock by the end of 2019 (80 FR 75432, December 2, 2015). In 2016, the SEDAR 33 Update assessment was completed and showed that greater amberjack was still overfished and undergoing overfishing as of 2015 and the stock would not be rebuilt by 2019 as previously projected. In 2017, NMFS notified the Council that the stock was not making adequate progress towards rebuilding and the Council developed a framework action to modify the rebuilding time and the catch levels. The framework action, which was implemented in 2018, reduced sector ACLs and ACTs in an effort to end overfishing and rebuild the stock by 2027 (82 FR 61485, December 28, 2017).

The SEDAR 70 assessment for Gulf greater amberjack was completed in November 2020, and indicated that the Gulf greater amberjack stock continued to be overfished and undergoing overfishing, but could rebuild by 2027 with reduced yields. NMFS informed the Council of these determinations in a letter dated April 7, 2021, and the Council began work on Amendment 54 to update the greater amberjack rebuilding plan.

The SEDAR 70 assessment used updated recreational catch and effort data from the Marine Recreational Information Program (MRIP) Access Point Angler Intercept Survey (APAIS) and Fishing Effort Survey (FES). MRIP began incorporating a new survey design for APAIS in 2013 and replaced the Coastal Household Telephone Survey (CHTS) with FES in 2018. Prior to the implementation of MRIP in 2008, recreational landings estimates were generated using the Marine Recreational Fisheries Statistics Survey (MRFSS). As explained in Amendment 54, total recreational fishing effort estimates generated from MRIP–FES are generally higher than both the MRFSS and MRIP–CHTS estimates. Although both MRIP–CHTS and MRIP–FES generate estimates measured in pounds of fish, these estimates are not directly comparable. To signify that the estimates use different scales, this rule uses the terms ''MRIP–CHTS units'' and ''MRIP–FES units'' to describe the recreational catch limits. To illustrate the difference in the survey estimates, the Southeast Fisheries Science Center (SEFSC) conducted an analysis to determine what the current greater amberjack stock ACL of 1,794,000 lb (813,745 kg) (MRIP–CHTS units) would be in MRIP–FES units. That analysis showed that greater amberjack stock ACL would be estimated at 2,930,000 lb (1,329,026 kg) (MRIP–FES units). This difference in the stock ACL is because MRIP–FES is designed to more accurately measure fishing effort, not because there was a sudden increase in fishing effort.

Based on the results of SEDAR 70, the Council's SSC recommended a decrease in the overfishing level (OFL) and acceptable biological catch (ABC) to end overfishing of greater amberjack and allow the stock to meet its current rebuilding time. Since these catch level recommendations assumed status quo sector allocations (27 percent commercial and 73 percent recreational), which were based in part on 1981–2004 landings estimates generated using data generated by MRFSS, the Council requested that the SEFSC provide alternative catch level projections based on sector allocation alternatives that used MRIP–FES data and several different time series: the same time series used in Amendment 30A (1981–2004); a time series that begins when commercial greater amberjack landings were identified by species and ends prior to the implementation of the current sector allocations, sector catch limits, and AMs (1993–2007); and a time series that begins when commercial greater amberjack landings were identified by species and ends with the most recent data available at the time the alternatives were developed (1993–2019). The Council's SSC reviewed these alternative sector allocation analysis and affirmed its prior determination that SEDAR 70 represented, and the projections produced by the assessment are, the best scientific information available.

The commercial and recreational allocation percentages impact the catch level projections. As more of the stock ACL is allocated to the recreational sector, the proportion of recreational discards increases. The recreational discard mortality rate (10 percent) is assumed to be less than the commercial discard mortality rate (20 percent). However, the magnitude of recreational discards is considerably greater than commercial discards because there are more recreational fishermen. Generally, a fish caught and released by a recreational fishermen has a greater likelihood of survival than a fish released by a commercial fishermen because of the differences in how and where the sectors fish. However, because of the greater numbers of greater amberjack that are released by the recreational sector versus the commercial sector, the total number of discards that die from the recreational fishing exceeds those attributed to commercial fishing. This results in additional mortality for the stock and a lower projected annual yield, which results in a reduced OFL, ABC, and stock ACL. However, this is not a result

of any change in how the recreational sector prosecutes the fishery but occurs because MRIP–FES estimates higher levels of fishing effort, and consequently a greater number of fish being caught, which includes discards and the associated mortality of discarding fish.

In Amendment 54, the Council considered several sector allocation alternatives: maintaining the current allocation percentages, and using the various time series reviewed by the SSC to adjust the allocation to reflect the most recent understanding of historical landings. The Council recognized that all of these alternatives are reasonably calculated to promote conservation of the greater amberjack stock because they would modify the allowable harvest consistent with the result of SEDAR 70 and the SSC's recommendations, which is expected to allow the stock to rebuild by 2027. In considering the fairness and equity of the allocation alternatives, the Council recognized that maintaining the current percentages would disproportionally impact on the recreational sector given the transition to MRIP–FES and that maintaining the current time series updated with MRIP–FES data would disproportionally impact the commercial sector by failing to account for the fact that commercial landings of greater amberjack prior to 1993 may not have been properly identified. The Council decided to adjust the allocation in Amendment 54 using the 1993–2019 time series because this represents the longest time series during which commercial greater amberjack landings have been identified by species. This results in a shift of the commercial and recreational allocation from 27 percent and 73 percent, respectively, to 20 percent and 80 percent, respectively.

The catch levels recommended by the SSC would increase the allowable harvest each year through the end of the rebuilding plan in 2027. However, the Council determined that because the greater amberjack stock has not rebuilt as expected under the current and previous rebuilding plans, a more cautious approach is necessary. Therefore, Amendment 54 and this proposed rule would adopt a constant catch strategy and modify the OFL and ABC to be 2,033,000 lb (922,153 kg) and 505,000 lb (229,064 kg), respectively. The stock ACL would be equal to the ABC.

Management Measures Contained in This Proposed Rule

If implemented, this proposed rule would revise the sector ACLs and ACTs for Gulf greater amberjack.

ACLs

The current stock ACL for Gulf greater amberjack is equal to the ABC of 1,794,000 lb (813,745 kg), and the current sector ACLs for Gulf greater amberjack are 484,380 lb (219,711 kg) for the commercial sector and 1,309,620 lb (594,034 kg) for the recreational sector. These catch levels are based on the results of SEDAR 33 Update, which used data from MRIP–CHTS. As explained above, had the current stock ACL been derived using MRIP–FES data, it would have been 2,930,000 lb (1,329,026 kg). This rule would reduce the stock ACL for Gulf greater amberjack to 505,000 lb (229,064 kg). Applying the allocation selected by the Council in Amendment 54 results in a proposed commercial ACL of 101,000 lb (45,813 kg) and a proposed recreational ACL of 404,000 lb (183,251 kg).

ACTs

The Council applied its ACL/ACT Control Rule using landings data for 2013–2016 to set the current commercial and recreational sector buffers between the ACL and ACT. This results in reduction in the buffer between the commercial ACL and ACT from 13 percent to 7 percent. The buffer between the recreational ACL and ACT remains at 17 percent. Applying these buffers results in a proposed commercial ACT of 93,930 lb (42,606 kg) and a proposed recreational ACT of 335,320 lb (152,099 kg).

Management Measures in Amendment 54 Not Codified Through This Proposed Rule

OFL and ABC

The current OFL and ABC for Gulf greater amberjack are 2,167,000 lb (982,935 kg) and 1,794,000 lb (813,745 kg), respectively, and are based on the Council's SSC's recommendations from the SEDAR 33 Update, which used recreational landings estimates from MRIP–CHTS. Amendment 54 would use a constant catch OFL and ABC based on SEDAR 70 and consistent with the SSC's recommendations. The revised OFL would be 2,033,000 lb (922,153 kg) and the revised ABC would be 505,000 lb (229,064 kg).

Sector Allocations

The current sector allocation of the stock ACL (equal to the ABC) is 27 percent to the commercial sector and 73 percent to the recreational sector. Amendment 54 would revise the Gulf greater amberjack allocation between the commercial and recreational sectors by using the average landings from 1993–2019 using MRIP–FES landings for this time series. This results in a new allocation of the Gulf greater amberjack stock ACL of 20 percent for the commercial sector and 80 percent for the recreational sector.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Amendment 54, the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. The Magnuson-Stevens Act provides the legal basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting and record-keeping requirements are introduced by this proposed rule. This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

NMFS prepared an initial regulatory flexibility analysis (IRFA) for this proposed rule, as required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of this proposed rule, why it is being considered, and the purposes of this proposed rule are contained in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of the preamble. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The objectives of this proposed rule are to end overfishing and rebuild the greater amberjack stock as required by the Magnuson-Stevens Act, and update existing greater amberjack catch limits and allocations to be consistent with the best scientific information available, FMP objectives, and contemporary data collection methods. All monetary estimates in the following analysis are in 2020 dollars.

This proposed rule would revise the sector allocations of the total ACL for Gulf greater amberjack from 73 percent for the recreational sector and 27 percent for the commercial sector to 80 percent for the recreational sector and 20 percent for the commercial sector. The current OFL, ABC, and total ACL are 2.167 million lb (982,935 kg), 1.794 million lb (813,745 kg), and 1.794 million lb (813,745 kg), respectively. The recreational portion of these values are based on MRIP–CHTS data. This proposed rule would change the OFL

and ABC to 2.033 million lb (922,153 kg) and 505,000 lb (229,064 kg), respectively, consistent with the results of the most recent stock assessment and the recommendations of the Council's SSC, and set the total ACL equal to the ABC of 505,000 lb (229,064 kg). The recreational portion of these values are based on MRIP–FES data. Applying the new sector allocations would change the recreational ACL from 1,309,620 lb (594,033 kg) in MRIP–CHTS units to 404,000 lb (183,251 kg) in MRIP–FES units and reduce the commercial ACL from 484,380 lb (219,675 kg) to 101,000 lb (45,812 kg). This proposed rule would retain the current 17 percent buffer between the recreational ACL and ACT. As such, the recreational ACT would be revised from 1,086,985 lb (493,048 kg) in MRIP–CHTS units to 335,320 lb (152,099 kg) in MRIP–FES units given the proposed reduction in the recreational ACL. This proposed rule would also decrease the buffer between the commercial ACL and ACT from 13 percent to 7 percent, and thereby reduce the commercial ACT from 421,411 lb (191,148 kg) to 93,930 lb (42,606 kg) given the proposed reduction in the commercial ACL. As a result, this proposed rule is expected to regulate commercial and charter vessel/headboat (for-hire) fishing businesses that harvest Gulf greater amberjack.

A valid commercial Gulf reef fish vessel permit is required in order for commercial fishing vessels to legally harvest greater amberjack in the Gulf. At the end of 2020, 837 vessels possessed a valid commercial Gulf reef fish vessel permit. However, not all vessels with a commercial Gulf reef fish permit actually harvest greater amberjack in the Gulf. From 2016 through 2020, the average number of vessels that commercially harvested Gulf greater amberjack was 201. Ownership data regarding vessels that harvest Gulf greater amberjack is incomplete. Therefore, accurately determining affiliations between these particular vessels is not currently feasible. Because of the incomplete ownership data, for purposes of this analysis, NMFS assumes each of these vessels is independently owned by a single business, which NMFS expects to result in an overestimate of the actual number of businesses directly regulated by this proposed action. Thus, NMFS assumes this proposed rule would regulate and directly affect 201 commercial fishing businesses.

Although the proposed changes to the recreational ACL and ACT would apply to recreational anglers, the RFA does not consider recreational anglers to be entities. Small entities include small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601(6) and 601(3)–(5)). Recreational anglers are not businesses, organizations, or governmental jurisdictions and so they are outside the scope of this analysis (5 U.S.C. 603).

A valid charter vessel/headboat Gulf reef fish vessel permit is required in order for for-hire vessels to legally harvest greater amberjack in the Gulf. NMFS does not possess complete ownership data regarding vessels that hold charter vessel/headboat Gulf reef fish vessel permits, and thus potentially harvest greater amberjack. Therefore, accurately determining affiliations between these vessels and the businesses that own them is not currently feasible. As a result, for purposes of this analysis, NMFS assumes each for-hire vessel is independently owned by a single business, which NMFS expects to result in an overestimate of the actual number of for-hire fishing businesses regulated by this proposed rule.

This proposed rule would only be expected to alter the fishing behavior of for-hire vessels that target greater amberjack in the Gulf (*i.e.,* the behavior of for-hire vessels that incidentally harvest greater amberjack in the Gulf is not expected to change). Therefore, only for-hire vessels that target greater amberjack in the Gulf are expected to be directly affected by this proposed regulatory action. NMFS does not possess data indicating how many for-hire vessels actually harvest or target Gulf greater amberjack in a given year. However, in 2020, there were 1,289 vessels with valid charter vessel/headboat Gulf reef fish vessel permits. Further, Gulf greater amberjack is primarily targeted in waters off the west coast of Florida. Of the 1,289 vessels with valid charter vessel/headboat Gulf reef fish vessel permits, 803 were homeported in Florida. Of these permitted vessels, 62 are primarily used for commercial fishing rather than for-hire fishing purposes and thus are not considered for-hire fishing businesses. In addition, 46 of these permitted vessels are considered headboats, which are considered for-hire fishing businesses. However, headboats take a relatively large, diverse set of anglers to harvest a diverse range of species on a trip, and therefore do not typically target a particular species. Therefore, NMFS assumes that no headboat trips would be canceled, and thus no headboats would be directly affected as a result of this proposed regulatory action. However, charter vessels often target greater amberjack. Of the 803 vessels with valid charter vessel/headboat Gulf reef fish vessel permits that are homeported in Florida, 695 vessels are charter vessels. A recent study reported that 76 percent of charter vessels with valid charter vessel/headboat permits in the Gulf were active in 2017 (*i.e.,* 24 percent were not fishing). A charter vessel would only be directly affected by this proposed rule if it is fishing. Given this information, the best estimate of the number of charter vessels that are likely to target Gulf greater amberjack in a given year is 528. Thus, this proposed rule is estimated to regulate and directly affect 528 for-hire fishing businesses.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (50 CFR 200.2). A business primarily involved in the commercial fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts (revenue) are not in excess of $11 million for all of its affiliated operations worldwide. From 2016 through 2020, the maximum annual gross revenue earned by a single commercial reef fish vessel during this time was about $1.73 million, while the average annual gross revenue for a vessel commercially harvesting Gulf greater amberjack was $190,612. Based on this information, all commercial fishing businesses regulated by this proposed rule are determined to be small entities for the purpose of this analysis.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the U.S., including for-hire businesses (NAICS code 487210). A business primarily involved in for-hire fishing 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 annual receipts (revenue) not in excess of $14 million for all its affiliated operations worldwide. NMFS does not have the necessary data to estimate the maximum annual gross revenue for all regulated charter vessels. However, the maximum annual gross revenue for a single headboat in the Gulf was about $1.38 million in 2017. On average, annual gross revenue for headboats in the Gulf is about three times greater than annual gross revenue for charter vessels. Based on this information, all for-hire fishing businesses regulated by this proposed rule are determined to be small businesses for the purpose of this analysis.

If implemented, NMFS expects this proposed rule to directly affect 201 of the 837 vessels with commercial Gulf reef fish permits, or approximately 24 percent of those commercial fishing businesses. Further, this proposed rule is expected to directly affect 528 of the 1,227 for-hire fishing businesses with valid charter vessel/headboat permits in the Gulf reef fish fishery, or approximately 43 percent of those for-hire fishing businesses. All regulated commercial and for-hire fishing businesses have been determined, for the purpose of this analysis, to be small entities. Based on this information, the proposed rule is expected to affect a substantial number of small businesses.

For vessels that commercially harvest greater amberjack in the Gulf, currently available data indicates that economic profits are approximately 38 percent of annual average gross revenue. Given that their average annual gross revenue is $190,612, annual average economic profit per vessel is estimated to be approximately $72,433. The proposed action to change the sector allocations and the total ACL would reduce the commercial ACL and thus also reduce the commercial ACT (commercial quota). The commercial quota, which is used to constrain harvest, would decrease from 421,411 lb (191,149 kg) to 87,870 lb (39,857 kg). However, average commercial landings of Gulf greater amberjack were 429,113 lb (194,642 kg) from 2015–2019. Thus, the reduction in commercial landings is expected to be 341,243 lb (154,785 kg), or 328,119 lb (148,832 kg), gutted weight. This reduction in commercial landings is not expected to increase the average ex-vessel price due to the relatively high number of substitute products (*e.g.,* imports, other reef fish species landed in the Gulf and South Atlantic, *etc.*). Thus, assuming the average ex-vessel price of $1.92 per lb gutted weight from 2016–2020, annual gross revenue is expected to decrease by $629,988, and economic profit is expected to decrease by $239,395. On a per vessel basis, annual gross revenue and economic profit are expected to decrease by $3,134 and $1,191, respectively.

Based on the most recent information available, average annual economic profits are approximately $27,000 per charter vessel. The proposed action to change the sector allocations and the total ACL would revise the recreational ACL and thus also revise the recreational ACT, which is used to constrain harvest. The proposed change to the recreational ACT is expected to change the length of the recreational fishing season. The proposed recreational ACT reduction is expected to reduce the recreational season length from 123 days to 20 days. From 2018 through 2021, the average number of trips targeting Gulf greater amberjack by charter vessels was 14,379. The expected number of target trips under the projected season length of 20 days is 1,221 trips, and thus target trips are expected to decline by 13,158 trips. Net Cash Flow per Angler Trip (CFpA) is the best available estimate of profit per angler trip by charter vessels. CFpA on charter vessels is estimated to be $143 per angler trip. Thus, the estimated reduction in charter vessel profits from this action is expected to be about $1.882 million, or $3,564 per for-hire fishing business. Thus, economic profits are expected to be reduced by more than 13 percent on average per for-hire fishing business.

The proposed action to reduce the buffer between the commercial ACL and ACT from 13 percent to 7 percent is expected to increase the commercial ACT by 6,060 lb (2,749 kg), or 5,827 lb (2,643 kg), gutted weight, relative to what it would be under the proposed action to decrease the commercial ACL. Given the significant reduction in the commercial ACL relative to recent average commercial landings, these additional pounds are expected to be harvested. The expected increase in commercial landings is expected to increase average annual gross revenue by $11,188 and thus economic profit by $4,251. On a per vessel basis, annual gross revenue and economic profit are expected to increase by $56 and $21, respectively.

Based on the proposed action to reduce the commercial catch limits and the proposed reduction in the buffer between the commercial ACL and ACT, the total reductions in gross revenue and economic profits for commercial fishing businesses from this proposed rule are expected to be $618,800 and $235,144, respectively. On a per vessel basis, the total reductions in annual gross revenue and economic profit are expected to be $3,079 and $1,170, respectively. Thus, economic profits are expected to be reduced by approximately 1.6 percent on average per commercial fishing business.

Five alternatives, including the status quo, were considered for the proposed action to revise the sector allocations, OFL, ABC, total ACL, and sector ACLs for greater amberjack in the Gulf. The first alternative, the status quo, would have retained the current allocation of the total ACL between the recreational and commercial sectors at 73 percent and 27 percent, respectively. It also would have maintained the OFL, ABC, total ACL, recreational ACL, and commercial ACL at 2.167 million lb (982,935 kg), 1.794 million lb (813,745 kg), 1.794 million lb (813,745 kg), 1,309,620 lb (594,033 kg), and 484,380 lb (219,675 kg). This alternative was not selected as it would not be based on the best scientific information available and therefore is inconsistent with National Standard 2 of the Magnuson-Stevens Act. Further, this alternative is inconsistent with the SSC's OFL and ABC recommendations.

The second alternative would have maintained the allocation of the total ACL at 73 percent recreational and 27 percent commercial. This alternative would have also revised the OFL and ABC as recommended by the SSC based on this sector allocation and the most recent stock assessment, set the total ACL equal to the ABC, and increased the OFL, ABC, total ACL, and sector ACLs each year through 2027. This alternative would be based on the best scientific information available and is consistent with the SSC's OFL and ABC recommendations. However, this alternative was not selected by the Council because it is partly based on MRFSS data, which significantly underestimates historical landings and effort in the recreational sector and thus does not accurately reflect the importance of Gulf greater amberjack to the recreational sector during the time period used as the basis for the status quo allocation (*i.e.,* 1981–2004).

The third alternative would have revised the allocation of the total ACL to 84 percent recreational and 16 percent commercial based on landings from the same timeframe as the status quo allocation (*i.e.,* 1981–2004), but using recreational landings based on MRIP–FES data. This alternative would have also revised the OFL and ABC as recommended by the SSC based on this sector allocation and the most recent stock assessment, set the total ACL equal to the ABC, and increased the OFL, ABC, total ACL, and sector ACLs each year through 2027. The Council recognized that the greater amberjack stock is overfished and has not rebuilt as expected under the current and previous rebuilding plans. This alternative was not selected by the Council because the allocation is based on years during which commercial landings of greater amberjack were not identified at the species level. In addition, the catch limits increased over time and the Council determined that a more cautious approach was warranted with respect to establishing future catch levels.

The fourth alternative would have revised the allocation of the total ACL to 78 percent recreational and 22

percent commercial based on MRIP–FES average landings during the years 1993 through 2007. This alternative would have also revised the OFL and ABC as recommended by the SSC based on this sector allocation and the most recent stock assessment, set the total stock ACL equal to the ABC, and increased the OFL, ABC, total ACL, and sector ACLs each year through 2027. The Council recognized that the greater amberjack stock is overfished and has not rebuilt as expected under the current and previous rebuilding plans. This alternative was not selected by the Council because the allocation does not include the more recent years, which reflect current participation. In addition, the catch limits would increase over time and the Council determined that a more cautious approach was warranted with respect to establishing future catch levels.

The fifth alternative would have revised the allocation of the total ACL to 80 percent recreational and 20 percent commercial based on MRIP–FES average recreational landings during the years 1993 through 2019. This alternative would have also revised the OFL and ABC as recommended by the SSC based on this sector allocation and the most recent stock assessment, set the total stock ACL equal to the ABC, and increased the OFL, ABC, total ACL, and sector ACLs each year through 2027. The Council did not select this alternative because the greater amberjack stock is overfished and has not rebuilt as expected under the current and previous rebuilding plans. Therefore, the Council determined that a more cautious approach was warranted with respect to establishing future catch levels.

Two alternatives, including the status quo, were considered for the proposed action to decrease the buffer between the commercial ACL and ACT from 13 percent to 7 percent. The first alternative, the status quo, would have retained the current 13 percent buffer. This alternative was not selected by the Council because it is based on commercial landings data from 2013–2016 and more recent commercial landings data are available and considered to be more representative of current commercial fishing practices.

The second alternative would have reduced the buffer between the commercial ACL and ACT from 13 percent to 7 percent, but would have also reduced the recreational buffer from 17 percent to 13 percent, based on landings data from 2017–2020. This alternative was not selected by the Council because landings in 2020 were likely affected by the COVID–19 pandemic, as reflected by the lack of closures that are common in this fishery, and thus likely not representative of typical recreational fishing practices.

List of Subjects in 50 CFR Part 622

Annual catch limits, Commercial, Fisheries, Fishing, Greater amberjack, Gulf of Mexico, Recreational.

Dated: March 6, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.39, revise paragraphs (a)(1)(v) and (a)(2)(ii) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(v) Greater amberjack—93,930 lb (42,606 kg), round weight.

* * * * *

(2) * * *

(ii) *Recreational quota for greater amberjack.* The recreational quota for greater amberjack is 335,320 lb (152,099 kg), round weight.

* * * * *

■ 3. In § 622.41, revise paragraphs (a)(1)(iii) and (a)(2)(iii) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

(a) * * *

(1) * * *

(iii) The commercial ACL for greater amberjack, in round weight, is 101,000 lb (45,813 kg).

(2) * * *

(iii) The recreational ACL for greater amberjack, in round weight, is 404,000 lb (183,251 kg).

* * * * *

[FR Doc. 2023–04913 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 88, No. 47
Friday, March 10, 2023

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

[Docket Number: USDA–2023–0004]

Submission for OMB Review; Comment Request

AGENCY: Office of the Chief Information Officer, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces and requests comments on the intention of the Office of the Chief Information Officer (OCIO) to request approval for the continuation of the U.S. Department of Agriculture (USDA) Registration Form to Request Electronic Access Code information collection to allow USDA customers to securely and confidently share data and receive services electronically. Authority for obtaining information from customers is included in the Freedom to E-File Act, the Electronic Signatures in Global and National Commerce Act (E–SIGN), the E-Government Act of 2002, and the GRAMM–LEACH–BLILEY ACT. Customer information is collected through the USDA eAuthentication Service (eAuth), located at *https://www.eauth.usda.gov.* The USDA eAuth service provides both public citizens as well as Federal Government employees with a secure single sign-on capability for USDA applications, management of user credentials, and verification of identity, authorization, and electronic signatures. USDA's eAuth Service obtains customer information through an electronic self-registration process provided through the eAuth website. This voluntary online self-registration process and identity proofing process (either in-person at a USDA Service Center or online with national credit bureaus) enables USDA customers to obtain accounts as authorized users that will provide single sign-on capability, self-registration, and account management to access USDA Web applications and services via the internet.

DATES: Comments on this notice must be received on or May 9, 2023 to be assured of consideration.

ADDRESSES:

▪ *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

▪ Interested persons are invited to submit comments concerning this information collection to Adam Zeimet, 2150 Centre Avenue, Building A-Suite 350, Fort Collins, Colorado 80526. Fax comments should be sent to the attention of Adam Zeimet at fax number (970) 295–5238.

FOR FURTHER INFORMATION CONTACT: Adam Zeimet by telephone at (970) 295–5678, or via email at *Adam.Zeimet@usda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), this notice announces the intention of USDA–OCIO–Customer Experience Center-Identity and Access Services Branch (Identity, Credential, and Access Management Program) to request approval for an existing collection.

Title: USDA Registration Form to Request Electronic Access Code.

OMB Number: 0503–0014.

Expiration Date of Approval: 6/30/2023.

Type of Request: Extension of a currently approved information collection.

Abstract: The USDA–OCIO developed the eAuthentication Service as a management and technical process that addresses user authentication and authorization prerequisites for providing services electronically. The process requires a one-time electronic self-registration to obtain an eAuthentication account for each USDA customer desiring access to on-line services or applications that require user authentication. USDA customers may self-register for an account in accordance with OMB Memorandum M–19–17 and National Institute of Standards and Technology Special Publication 800–63–3 (or superseding publications). An eAuthentication account, without identity verification, provides users with limited access to USDA website portals and applications that have minimal security requirements. A customer with an eAuthentication account, with identity verification, is permitted to conduct official electronic business transactions via the internet, enter into a contract with the USDA, and submit forms electronically via the internet to USDA agencies. Due to the increased risk associated with these types of transactions, the identity of customers must be verified through a process called ''identity proofing''. Identity proofing can be accomplished for USDA customers in two ways: (1) By visiting a Local Registration Authority (LRA) at a USDA Service Center; or (2) Through an integrated online identity proofing service with a National Credit Bureau. The on-line identity proofing service provides registrants with a more efficient mechanism for identity verification. On-line identity proofing requires responses to at least four randomly selected identity questions that are verified by a national credit bureau identity proofing service in an automated interface. Once the user's identity if verified, they may use the associated credential to access USDA resources that utilize eAuthentication services.

Estimate of Burden: Public reporting burden for this collection of information is estimated to take three (3) minutes to complete the self-registration process for an eAuthentication account, without identity verification. With an estimated 235,092 respondents, the annual public burden time is 11,754.60 hours (235,092 * (3/60)). Customers needing a higher form of access are required to provide additional information for identity proofing purposes. The data entry for identity verification is estimated to take three (3) minutes. With an estimated 72,912 respondents, the annual public burden time is 3,645.60 hours (72,912 * (3/60)). For identity verification through a LRA, the time is estimated to take one (1) hour to travel to a USDA Service Center to visit a Local Registration Authority (expected to be approximately 9% of the registrants). With an estimated 6,562 respondents, the annual public burden time is 6,562 hours (6,562

* (60/60)). For online identity verification, the time is estimated to take five (5) minutes (expected to be approximately 91% of the registrants). With an estimated 66,350 respondents, the annual public burden time is 5,308 hours (66,350 * (5/60)). The total estimated annual public burden rate is 27,270.20 hours (11,754.60 + 3,645.60 + 6,562 + 5,308) = 27,270.20).

Respondents: Individual USDA customers.

Estimated Number of Respondents per account type:

- eAuthentication account, without identity proofing: 235,092.
- eAuthentication account, with identity proofing: 72,912.
  - In Person ID Proofing (9%): 6,562.
  - Online\Remote ID Proofing (91%): 66,350.

Estimated Total Number of Respondents: 308,004.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 27,270.2 hours.

Comments are invited on (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of the information on those who respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods. Copies of the information collection may be obtained from Mr. Zeimet by calling or emailing your request to the contact information above in the **FOR FURTHER INFORMATION CONTACT** section. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Gary Washington,

Chief Information Officer, Office of the Chief Information Officer.

[FR Doc. 2023–04977 Filed 3–9–23; 8:45 am]

BILLING CODE 3410–KR–P

DEPARTMENT OF AGRICULTURE

Forest Service

Request for Applications: The Community Forest and Open Space Conservation Program

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Request for applications.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, State and Private Forestry, Cooperative Forestry staff, requests applications for the Community Forest and Open Space Conservation Program (Community Forest Program or CFP). This is a competitive grant program whereby local governments, qualified nonprofit organizations, and Indian tribes are eligible to apply for grants to establish community forests through the fee simple acquisition of private forest land from a willing seller.

DATES: Interested local government and nonprofit applicants must submit applications to the State Forester. Tribal applicants must submit applications to the appropriate Tribal government officials. All applications, either hardcopy or electronic, must be received by State Foresters or Tribal governments by March 31, 2023, State Foresters or Tribal government officials must forward applications to the appropriate Forest Service Regional office or International Institute of Tropical Forestry by April 14, 2023.

ADDRESSES: All local government and qualified nonprofit organization applications must be submitted to the State Forester of the State where the property is located. All Tribal applications must be submitted to the equivalent Tribal government official. Applicants are encouraged to contact and work with the Forest Service Region or International Institute of Tropical Forestry, and State Forester or equivalent Tribal government official when developing their proposal.

Applicants must consult with the State Forester and equivalent Tribal government official prior to requesting technical assistance for a project. The State Forester's member roster may be found on *https://www.stateforesters.org/who-we-are/our-membership/*. All applicants must also send an email to *SM.FS.CFP@usda.gov* to confirm an application has been submitted for funding consideration.

State Foresters and Tribal government officials shall submit applications, either electronic or hardcopy, to the appropriate Forest Service Region/Institute contact noted below. Applicants are encouraged to contact and work with a Forest Service Region/Institute during the application process and before submission. Forest Service staff can assist with navigating program requirements, determining eligibility, providing guidance on allowable costs and match, and other questions.

Northern and Intermountain Regions

Regions 1 and 4

(ID, MT, ND, NV, UT)

Kris Tempel, USDA Forest Service, 650 Wolfpack Way, Kalispell, MT 59901, 406–210–1412 (mobile), *kris.tempel@usda.gov*

Rocky Mountain Region

Region 2

(CO, KS, NE, SD, WY)

Todd Gardiner, USDA Forest Service, 1617 Cole Boulevard, Bldg. 17, Lakewood, CO 80401, 970–210–9103 (mobile), *todd.gardiner@usda.gov*

Southwestern Region

Region 3

(AZ, NM)

Laura Moser, USDA Forest Service, 333 Broadway SE, Albuquerque, NM 87102, 928–607–6040 (mobile), *laura.moser@usda.gov*

Pacific Southwest Region

Region 5

(CA)

Dana Walsh, USDA Forest Service, 1323 Club Drive, Vallejo, CA 94592, 530–450–5555 (mobile), *dana.walsh@usda.gov*

(Hawaii, Guam, American Samoa, Federated States of Micronesia and other Pacific Islands)

Katie Friday, USDA Forest Service, 60 Nowelo St., Hilo, HI 96720, 808–785–5197 (mobile), *kathleen.friday@usda.gov*

Pacific Northwest, and Alaska Regions

Regions 6 and 10

(AK, OR, WA)

Candice Polisky, USDA Forest Service, 1220 SW Third Ave., Portland, OR 97204, 971–710–2346 (mobile), *candice.polisky@usda.gov*

Southern Region

Region 8

(AL, AR, FL, GA, KY, LA, MS, NC, OK, SC, TN, TX, VA)

Susan Granbery, USDA Forest Service, 1720 Peachtree Rd. NW, Suite 700,

Atlanta, GA 30309, 770–883–8925 (mobile), *susan.granbery@usda.gov*

International Institute of Tropical Forestry

(PR, VI)

Magaly Figueroa, USDA Forest Service, Jardin Botanico Sur, 1201 Calle Ceiba, San Juan, PR 00926–1119, 787–309–9565 (mobile), *magaly.figueroa@usda.gov*

Eastern Region

Region 9

(CT, DC, DE, IA, IL, IN, MA, MD, ME, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, WI, WV)

Neal Bungard, USDA Forest Service, 271 Mast Road, Durham, NH 03824, 603–833–3287 (mobile), *neal.bungard@usda.gov*

FOR FURTHER INFORMATION CONTACT: For questions regarding the grant application or administrative regulations, contact Scott Stewart, Program Coordinator, 202–465–5038, *scott.stewart@usda.gov* or Margee Haines 202–384–7192, *margaret.haines@usda.gov.* Additional information about the Community Forest and Open Space Conservation Program may be obtained at *https://www.fs.usda.gov/managing-land/private-land/community-forest.*

Applicants are strongly encouraged to contact and work with the appropriate Forest Service Region/Institute contact during the application process before submission. Please contact the appropriate Forest Service Region/Institute if you would like review and feedback on your application and maps before submitting the final application. The final application is due to State Foresters or equivalent official or Tribal Governments by March 31, 2023. The Forest Service will host an informational webinar about the program and how to apply. For more information, please see the national web page at the link above.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 800–877–8339 between 8 a.m. and 8 p.m., 24 hours a day, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the program is to establish community forests by protecting forest land from conversion to non-forest uses and provide community benefits such as sustainable forest management, environmental benefits including clean air, water, and wildlife habitat; benefits from forest-based educational programs; benefits from serving as models of effective forest stewardship; and recreational benefits secured with public access.

Eligible lands for grants funded under this program are private forest that is at least five acres in size, suitable to sustain natural vegetation, and at least 75 percent forested. The lands must also be threatened by conversion to non-forest uses, must not be held in trust by the United States on behalf of any Indian Tribe, must not be Tribal allotment lands, must be offered for sale by a willing seller, and if acquired by an eligible entity, must provide defined community benefits under CFP and allow public access.

CFDA number 10.689: To address the goals of section 7A of the Cooperative Forestry Assistance Act of 1978 (16 U.S.C. 2103d) as amended, the Forest Service is requesting proposals for community forest projects that protect forest land that has been identified as a national, regional, or local priority for protection and to assist communities in acquiring forestland that will provide public recreation, environmental and economic benefits, and forest-based educational programs.

Detailed information regarding what to include in the application, definitions of terms, eligibility, and necessary prerequisites for consideration can be found in the final program rule, published April 2, 2021 (86 FR 17302), which is available at *https://www.fs.usda.gov/managing-land/private-land/community-forest/program.*

Grant Application Requirements

1. Eligibility Information

a. *Eligible Applicants.* A local governmental entity, Federally Recognized Indian Tribe (including Alaska Native Corporations), or a qualified nonprofit organization that is qualified to acquire and manage land. Individuals are not eligible to receive funds through this program.

b. *Cost Sharing (Matching Requirement).* All applicants must demonstrate a 50 percent match of the total project cost. The match can include cash, in-kind services, or donations, which shall be from a non-Federal source. For additional information, please see 36 CFR 230.6.

c. *DUNS Number.* All applicants shall include a Data Universal Numbering System (DUNS) number in their application. For this requirement, the applicant is the entity that meets the eligibility criteria and has the legal authority to apply for and receive the grant. For assistance in obtaining a DUNS number at no cost, call the DUNS number request line 1–866–705–5711 or register on-line at *http://fedgov.dnb.com/webform.*

d. *System for Award Management.* All prospective awardees shall be registered in the System for Award Management (SAM) prior to award, during performance, and through final payment of any grant resulting from this solicitation. Further information can be found at: *https://www.sam.gov/SAM/.* For assistance, contact Federal Service Desk 866–606–8220.

2. Award Information

Individual grant applications may not exceed $600,000 in requested federal funding, which does not include technical assistance requests. Grant applications must also include at least 50 percent non-federal cost share.

No legal liability on the part of the Government shall be incurred until funds are obligated by the grant officer for this program to the applicant in writing. The initial grant period shall be for two years, and acquisition of lands should occur within that timeframe. Lands acquired prior to the grant award are not eligible for CFP funding. The grant may be reasonably extended by the Forest Service when necessary to accommodate unforeseen circumstances in the land acquisition process. Written annual financial performance reports and semi-annual project performance reports shall be required and submitted to the appropriate grant officer.

Technical assistance funds, totaling not more than 10 percent of all funds, may be allocated to State Foresters or equivalent officials of Indian Tribes. Technical assistance, if provided, will be awarded at the time of the grant. Applicants shall work with State Foresters or equivalent officials of Indian Tribes to determine technical assistance needs and include the technical assistance request in the project budget.

As funding allows, applications submitted through this request may be funded in future years, subject to the availability of funds and the continued feasibility and viability of the project. If an application is successful, it may be shared as a replicable model with future interested applicants.

3. Application Information

Application submission. All local governments and qualified nonprofit organizations' applications must be submitted to the State Forester or equivalent official where the property is located by March 31, 2023. All Tribal applications must be submitted to the equivalent Tribal officials by March 31, 2023. Applications may be submitted

either electronically or in hardcopy to the appropriate official. The State Forester's contact information may be found at: *https://www.stateforesters.org/who-we-are/our-membership/.*

All applicants must also send an email to *SM.FS.CFP@usda.gov* for confirmation that an application has been submitted to the State Forester or equivalent Tribal official for funding consideration.

All State Foresters and Tribal government officials must forward all applications to the Forest Service by April 14, 2023.

4. Application Requirements

The following section outlines grant application requirements:

i. The application must be no more than eight pages long, plus no more than two maps (eight and half inches by eleven inches in size).

ii. Documentation verifying that the applicant is an eligible entity and that the land proposed for acquisition is eligible (see § 230.2 of the final rule).

1. Eligible Entities include local governmental entities, federally recognized Indian Tribes, and qualified nonprofit organizations.

2. Eligible lands are private forest lands that are threatened by conversion to non-forest use; not held in trust by the United States; provide defined community benefits; and are at least five acres in size, suitable to sustain natural vegetation, and at least 75 percent forested.

iii. Contact information for the project lead (name, title, phone number, email).

iv. Applications must include the following, regarding the property proposed for acquisition:

1. A description of the property, including acreage and county location;

2. A description of current land uses, including improvements;

3. A description of forest type and vegetative cover;

4. A map of sufficient scale to show the location of the property in relation to roads and other improvements as well as parks, refuges, green/open space, urban natural areas, or other protected lands in the vicinity;

5. A description of applicable zoning and other land use regulations affecting the property;

6. A description of the type and the extent of community benefits that the property will provide, including to underserved communities (see Project Selection Criteria);

7. A description of relationship of the property within and its contributions to landscape conservation initiatives, as well as any environmental justice initiatives, if applicable; and

8. A description of any threats of conversion to non-forest uses, including any encumbrances on the property that prevent conversion to non-forest uses.

v. Information regarding the proposed establishment of a community forest, including:

1. A description of the benefiting community, including:

a. Demographics, such as race or socioeconomic status

b. Availability of and access to green spaces, and other vulnerabilities including health, economic, environmental and climate impacts faced by the community

c. A description of how the project benefits the community and the associated benefits.

2. A description of community involvement, including underrepresented communities, to-date in the planning of the community forest acquisition, including determining access and use of the forest, and the participation of different community groups anticipated in long-term management.

3. An identification of persons and organizations that support the project, a description of how they represent the greater population of the community benefiting from the establishment and management of the community forest, their specific role in establishing and managing the community forest; and

vi. Information regarding the proposed land acquisition, including:

1. A proposed project budget not exceeding $600,000 and technical assistance needs as coordinated with the State Forester or equivalent Tribal government official (section § 230.6 of the final program rule);

2. The status of due diligence, including signed option or purchase and sale agreement, title search, minerals determination, and appraisal;

3. Description and status of cost share (secure, pending, commitment letter, etc.) (section § 230.6 of the final rule);

4. The status of negotiations with participating landowner(s) including purchase options, contracts, and other terms and conditions of sale;

5. The proposed timeline for completing the acquisition and establishing the community forest; and;

6. Long term management costs and funding source(s).

vii. Applications must comply with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR part 200).

In order to assist applicants, a Community Forest Road Map can be found on the CFP website at *https://www.fs.usda.gov/managing-land/private-land/community-forest/program.* The application guidance is located at *https://www.fs.usda.gov/sites/default/files/application-guidance-revised.pdf* and the scoring guidance is at *https://www.fs.usda.gov/sites/default/files/ScoringGuidance-revised.pdf.*

5. Forest Service's Project Selection Criteria

a. Using the criteria described below, to the extent practicable, the Forest Service will give priority to applications that maximize the delivery of community benefits, as defined in the final rule (see section § 230.2 of the final rule); and

b. The Forest Service will evaluate all applications received by the State Foresters or equivalent Tribal government officials and award grants based on the following criteria:

i. Type and extent of community benefits provided, including to underserved communities. Community benefits are defined in the final program rule as:

1. Economic benefits, such as timber and non-timber products resulting from sustainable forest management, recreation and tourism;

2. Environmental benefits, including clean air and water, stormwater management, wildlife habitat, and cultural resources.

3. Benefits from forest-based experiential learning, including K–12 conservation education programs; vocational education programs in disciplines such as forestry and environmental science; Traditional Ecological Knowledge; and environmental education through individual study or voluntary participation in programs offered by organizations such as 4–H, Boy or Girl Scouts, Master Gardeners, etc.;

4. Benefits from serving as replicable models of effective forest stewardship for private landowners; and

5. Recreational benefits such as hiking, hunting, and fishing secured through public access.

ii. Extent and nature of community engagement, including participation by underserved communities, in the establishment and long-term management of the community forest;

iii. Amount of other funds leveraged;

iv. Costs to the Federal Government,

v. Extent to which the community forest contributes to any landscape conservation initiatives, as well as any applicable environmental justice initiatives;

vi. Extent of due diligence completed on the project, including cost share

committed and status of appraisal and other due diligence costs;

vii. Likelihood that, unprotected, the property would be converted to non-forest uses; and

viii. Letters of support can accompany the application.

6. Grant Requirements

a. Once an application is selected, funding will be obligated to the grant recipient through a grant adhering to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR part 200).

b. Forest Service must approve any amendments to a proposal or request to reallocate funding within a grant proposal. If negotiations on a selected project fail, the applicant cannot substitute an alternative site.

c. The grant recipient must comply with the requirements in section § 230.8 in the final rule before funds will be released.

d. After the project has closed, as a requirement of the grant, grant recipients will be required to provide the Forest Service with a Geographic Information System (GIS) shapefile: a digital, vector-based storage format for storing geometric location and associated attribute information, of CFP project tracts and cost share tracts, if applicable.

e. Any funds not expended within the grant period must be de-obligated and revert to the Forest Service.

f. All media, press, signage, and other documents discussing the creation of the community forest must reference the partnership and financial assistance by the Forest Service through the CFP.

Dated: March 6, 2023.

Jaelith Hall-Rivera,

Deputy Chief, State and Private Forestry.

[FR Doc. 2023–04888 Filed 3–9–23; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Arkansas 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 Arkansas Advisory Committee (Committee) will hold a virtual (online) meeting Wednesday, March 8, 2023 at 12:00 p.m. Central Time. The purpose of the meeting is for the Committee to discuss the of the releasing of publication IDEA compliance and implementation in AR schools and related post-report activity.

DATES: The meeting will be held on Wednesday, March 8, 2023 at 12 p.m. Central time.

ADDRESSES:

Web Access (audio/visual): Register at: *https://www.zoomgov.com/j/1600743159.*

Phone Access (audio only): 833–435–1820, Meeting ID 160 074 3159.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may join online or listen to this discussion through the above registration link or 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. Closed captions will be provided. 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 Melissa Wojnaroski at *mwojnaroski@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, Arkansas 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
III. Committee Discussion: IDEA Compliance and Implementation in Arkansas Schools (Post-report)
IV. Next Steps
V. Public Comment
VI. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of DFO availability and pending leave.

Dated: March 6, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–04861 Filed 3–9–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Arkansas 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 Arkansas Advisory Committee (Committee) will hold a virtual (online) meeting Wednesday, March 8, 2023 at 12 p.m. Central Time. The purpose of the meeting is for the Committee to discuss the of the releasing of publication IDEA compliance and implementation in AR schools and related post-report activity.

DATES: The meeting will be held on Wednesday, March 8, 2023 at 12 p.m. Central time.

Web Access (audio/visual): Register at: *https://www.zoomgov.com/j/1600743159*

Phone Access (audio only): 833–435–1820, Meeting ID 160 074 3159

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may join online or listen to this discussion through the above registration link or 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. Closed captions will be provided. 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 Melissa Wojnaroski at *mwojnaroski@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, Arkansas 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
III. Committee Discussion: IDEA Compliance and Implementation in Arkansas Schools (Post-Report)
IV. Next Steps
V. Public Comment
VI. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of DFO availability and pending leave.

Dated: March 7, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–04993 Filed 3–9–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: Commission on the Social Status of Black Men and Boys (CSSBMB), U.S. Commission on Civil Rights.

ACTION: Notice of CSSBMB open discussion.

DATES: Tuesday, March 14, 2023. 1 p.m.–3 p.m. EDT.

ADDRESSES: The Briefing will take place virtually via YouTube: *https://www.youtube.com/user/USCCR/videos.*

FOR FURTHER INFORMATION CONTACT: Dr. Mark Spencer, *pressbmb@usccr.gov;* 202–376–7700.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 116–156, 1134 Stat. 700 (2020), the Commission on the Social Status of Black Men and Boys (CSSBMB) will hold an open discussion focused on preventative strategies to mitigate the social disparities of Black men in America.

This briefing is open to the public via livestream on the Commission on Civil Rights' YouTube Page at *https://www.youtube.com/user/USCCR/videos.* (Streaming information subject to change.) Public participation is available for the event with view access, along with an audio option for listening. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Tuesday, March 14, 2023, is *https://www.steamtext.net/player?event=USCCR* (*subject to change). Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

* Date and meeting details are subject to change. For more information on the CSSBMB or the upcoming public briefing, please visit CSSBMB's website at *www.usccr.gov/about/CSSBMB.*

Briefing Agenda

I. Opening Remarks by CSSBMB Chair, Frederica S. Wilson
II. Call to Order
III. Approval of Agenda
IV. Roundtable Discussion with Expert Panelists *
  A. The Honorable Frederica Wilson, Congresswoman (FL–24) and CSSBMB Chair
  B. The Honorable Steven Horsford, Congressman (NV–04) and CSSBMB Commissioner (Discussion Moderator)
  C. Dr. Sean Joe—Homegrown STL
  D. Arohi Pathak—Center for American Progress
  E. Dr. Rashawn Ray—The Brookings Institute
  F. Other Distinguished Guests
V. Adjourn Discussion

Dated: March 7, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit, USCCR.

[FR Doc. 2023–05049 Filed 3–8–23; 11:15 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; National Survey of Children's Health

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on December 8, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: National Survey of Children's Health.

OMB Control Number: 0607–0990.

Form Number(s): NSCH–S1 (English Screener), NSCH–T1 (English Topical for 0- to 5-year-old children), NSCH–T2 (English Topical for 6- to 11-year-old children), NSCH–T3 (English Topical for 12- to 17-year-old children), NSCH–S–S1 (Spanish Screener), NSCH–S–T1 (Spanish Topical for 0- to 5-year-old children), NSCH–S–T2 (Spanish Topical for 6- to 11-year-old children), and NSCH–S–T3 (Spanish Topical for 12- to 17-year-old children).

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 67,299 for the screener only and 65,103 for the combined screener and topical, for a total of 132,402 respondents.

Average Hours per Response: 5 minutes per screener response and 35–36 minutes per topical response, which in total is approximately 40–41 minutes for households with eligible children.

Burden Hours: 49,431.

Needs and Uses: The National Survey of Children's Health (NSCH) enables the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) along with supplemental sponsoring agencies, states, and other data users to produce national and state-based estimates on the health and well-being of children, their families, and their communities as well as estimates of the prevalence and impact of children with special health care needs.

Data will be collected using one of two modes. The first mode is a web instrument (Centurion) survey that contains the screener and topical instruments. The web instrument first will take the respondent through the screener questions. If the household screens into the study, the respondent will be taken directly into one of the

three age-based topical sets of questions. The second mode is a mailout/mailback of a self-administered paper-and-pencil interviewing (PAPI) screener instrument followed by a separate mailout/mailback of a PAPI age-based topical instrument.

The National Survey of Children's Health (NSCH) is a large-scale (sample size is up to 385,000 addresses) national survey with approximately 200,000 addresses included in the base production survey and approximately 185,000 addresses included as part of fifteen separate age-based, state-based, or region-based oversamples. The 2023 NSCH will include a topical incentive test. Prior cycles of the survey have included a $5 unconditional cash incentive with the initial mailing of the paper topical questionnaire. The incentive has proven to be a cost-effective intervention for increasing survey response and reducing nonresponse bias. The 2023 NSCH will continue to test a $10 cash incentive, with a focus on lower responding households.

As in prior cycles of the NSCH, there remain two key, non-experimental design elements. The first additional non-experimental design element is a $5 screener cash incentive mailed to 90% of sampled addresses; the remaining 10% (the control) will receive no incentive to monitor the effectiveness of the cash incentive. This incentive is designed to increase response and reduce nonresponse bias. The incentive amount was chosen based on the results of the 2022 NSCH as well as funding availability. The second additional non-experimental design element is a data collection procedure based on the block group-level paper-only response probability used to identify households (30% of the sample) that would be more likely to respond by paper and send them a paper questionnaire in the initial mailing.

Affected Public: Individuals or households.

Frequency: The 2023 collection is the eighth administration of the NSCH. It is an annual survey, with a new sample drawn for each administration.

Respondent's Obligation: Voluntary.

Legal Authority: Census Authority: Title 13, United States Code (U.S.C.), Section 8(b) (13 U.S.C. 8(b)).

HRSA MCHB Authority: Section 501(a)(2) of the Social Security Act (42 U.S.C. 701).

United States Department of Agriculture Authority: Agriculture Improvement Act of 2018, Public Law 115–334.

United States Department of Health and Human Services' Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities Authority: Public Health Service Act, Section 301, 42 U.S.C. 241.

United States Department of Health and Human Services' Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion Authority: Sections 301(a), 307, and 399G of the Public Health Service [42 U.S.C. 241(a), 242l, and 280e–11], as amended.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0990.

Sheleen Dumas,

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

[FR Doc. 2023–04932 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; The American Community Survey and Puerto Rico Community Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 13, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: The American Community Survey and the Puerto Rico Community Survey.

OMB Control Number: 0607–0810.

Form Number(s): ACS–1, ACS–1(SP), ACS–1(PR), ACS–1(PR)SP, ACS–1(GQ), ACS–1(PR)(GQ), GQFQ, ACS CAPI (HU), ACS RI (HU), AGQ QI, and AGQ RI.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 3,576,000 for household respondents; 20,100 for contacts in group quarters; 170,900 people in group quarters; 22,875 households for reinterview; and 1,422 group quarters contacts for reinterview. The total estimated number of respondents is 3,791,297.

Average Hours per Response: 40 minutes for the average household questionnaire; 15 minutes for a group quarters facility questionnaire; 25 minutes for a group quarters person questionnaire; 10 minutes for a household reinterview; 10 minutes for a group quarters-level reinterview.

Burden Hours: 2,384,000 for household respondents; 5,025 for contacts in group quarters; 71,208 for group quarters residents; 3,813 households for reinterview; and 237 group quarters contacts for reinterview. The estimate is an annual average of 2,464,283 burden hours.

Needs and Uses: The U.S. Census Bureau requests authorization from the OMB for revisions to the American Community Survey (ACS). The ACS is one of the Department of Commerce's most valuable data products, used extensively by businesses, nongovernmental organizations (NGOs), local governments, and many federal agencies. In conducting this survey, the Census Bureau's top priority is respecting the time and privacy of the people providing information while preserving its value to the public.

In 2024, the ACS plans to add internet self-response as an additional option to the group quarters data collection operation. The Census Bureau believes there is value in offering a self-response option to people living in certain types of group quarters—college/university student housing, group homes, military barracks, workers' group living quarters and Job Corps centers, and emergency and transitional shelters. The group quarters data collection operation will continue to offer paper, telephone, and in-person response options to collect data.

The Census Bureau is authorized by law (Title 13, U.S. Code) to use existing information that has already been collected by other government agencies, whenever possible and consistent with the kind, timeliness, quality, and scope of the statistics required, instead of asking for such information directly from the public. The Census Bureau is allowed to use these data for statistical purposes only and may not use these records for enforcement purposes or to decide on eligibility for a benefit. Additionally, Census Bureau research has shown that using administrative data can reduce respondent burden and improve the quality of the ACS data. In 2024, the Census Bureau will supplement or replace ACS survey data for the question asking about property acreage. The Census Bureau will continue research to explore how administrative data can be used for other items on the survey, with initial efforts focusing on other housing items, such as agricultural sales and year built.

In addition to using administrative records and in coordination with the Office of Management and Budget Interagency Committee for the ACS, the Census Bureau solicited proposals for question changes or additions from more than 20 federal agencies. Approved topics underwent cognitive testing to verify that proposed question wording would be understood by respondents. Based on cognitive testing results, the Census Bureau proposes to update wording in 2024 for questions on three topics: condominium fees, home heating fuel, and journey to work. The Census Bureau proposes to implement these three topics without additional testing; other topics are still undergoing testing.

The condominium fees question would be extended to include homeowners association (HOA) fees. Data sources continue to show housing units that are part of HOAs outnumber housing units in condominiums. In order to provide more comprehensive and accurate costs of owning a home, the ACS needs to capture HOA fees for these homes. Adding these fees to the existing condominium fees question avoids adding a new question to the ACS and therefore minimizes respondent burden.

The change to the home heating fuel question would update the natural gas and bottled gas categories. This will aid respondents in identifying the correct category more easily by using more commonly used terminology. In Puerto Rico, the question wording also changed to indicate respondents should only include fuel that heats their home.

The journey to work question would be updated to include ride-sharing services as a mode of transportation to work to account for new and growing travel trends. This will reduce ambiguity in the current question about where respondents should report ride-sharing commutes and will allow the government to monitor changes in transportation patterns for planning purposes.

Since the 60-day **Federal Register** Notice, Doc. 2022–19705, Volume 87, pages 55990–55993 posted on September 13, 2022, the Veterans Administration requested the ACS adjust the dates for the Vietnam War and Korean War to reflect the dates that they use for program evaluation (each period would be adjusted by one month). The Veterans Administration also requested that ''Post 9/11'' be added as a descriptor for the current service period; that ''Vietnam era'' be changed to ''Vietnam War''; and names of war periods be moved to the end of the date range for uniform appearance. The Veterans Administration requested that the date ranges use the word ''through'' instead of ''to'' for clarity. The updated dates for period of service will match the dates that the Veterans Administration uses for program evaluation as well as the official historical dates of war periods published by the Congressional Research Service. Moving names of war periods to the end of service categories will create a more uniform appearance of the question text, with dates listed first for all periods.

The addition of White and Black or African American write-in lines in the race question led the Census Bureau to research redundancies between data collected from the improved race question and the ancestry question. Findings from this research may lead the Census Bureau to recommend the removal of the ancestry question from the American Community Survey.

The Census Bureau developed the ACS to collect and update demographic, social, economic, and housing data every year that are essentially the same as the ''long-form'' data that the Census Bureau formerly collected once a decade as part of the decennial census. The ACS blends the strength of small area estimation with the high quality of current surveys. The ACS is an ongoing monthly survey that collects detailed housing and socioeconomic data from about 3.5 million addresses in the United States and about 36,000 addresses in Puerto Rico each year. The ACS also collects detailed socioeconomic data from about 170,000 residents living in group quarters facilities in the United States and about 900 in Puerto Rico. The ACS is now the only source of comparable data about social, economic, housing, and demographic characteristics for small areas and small subpopulations across the nation and in Puerto Rico. Every community in the nation continues to receive a detailed, statistical portrait of its social, economic, housing, and demographic characteristics each year through one-year and five-year ACS products.

To collect the ACS data, the Census Bureau uses a multiple mode contact strategy. These modes include mail, internet, telephone, and personal visit. To encourage self-response in the ACS, the Census Bureau sends up to five mailings to housing units selected to be in the sample. The first mailing, sent to all mailable addresses in the sample, includes an invitation to participate in the ACS online and states that a paper questionnaire will be sent in a few weeks to those unable to respond online. The second mailing is a letter that reminds respondents to complete the survey online, thanks them if they have already done so, and informs them that a paper form will be sent at a later date if the Census Bureau does not receive their response. In a third mailing, the questionnaire package is sent only to those sample addresses that have not completed the online questionnaire within two and a half weeks. The fourth mailing is a postcard that reminds respondents to respond and informs them that an interviewer may contact them if they do not complete the survey. A fifth mailing is a letter sent to respondents who have not completed the survey within five weeks. This letter provides a due date and reminds the respondents to return their questionnaires to be removed from future contact. The Census Bureau will ask those who fill out the survey online to provide an email address, which will be used to send an email reminder to households that did not complete the online form. The reminder asks them to log back in to finish responding to the survey. If the Census Bureau does not receive a response or if the household refuses to participate, the address may be selected for computer-assisted personal interviewing, the nonresponse follow-up data collection mode.

Some addresses are deemed unmailable because the address is incomplete or directs mail only to a post office box. The Census Bureau currently collects data for these housing units using both online and computer-assisted personal interviewing. A small sample of respondents from the nonresponse follow-up data collection interview are

recontacted for quality assurance purposes.

For sample housing units in the Puerto Rico Community Survey, a different mail strategy is employed. The Census Bureau continues to use the previously used mail strategy with no references to an internet response option. The Census Bureau sends up to five mailings to a Puerto Rico address selected to be in the sample. The first mailing includes a prenotice letter. The second and fourth mailings include the paper survey. The third and fifth mailings serve as a reminder to respond to the survey. Puerto Rico addresses deemed unmailable because the address is incomplete or directs mail only to a post office box are collected by computer-assisted personal interviewing. A small sample of respondents from the nonresponse follow-up data collection interview are recontacted for quality assurance purposes.

The Census Bureau uses a different strategy to collect data from group quarters. The Census Bureau defines group quarters as places where people live or stay, in a group living arrangement that is owned or managed by an entity or organization providing housing and/or services for the residents, such as college/university student housing, residential treatment centers, skilled nursing facilities, group homes, military barracks, correctional facilities, workers' group living quarters and Job Corps centers, and emergency and transitional shelters. The Census Bureau collects data for group quarters primarily through personal interview. The Census Bureau will obtain the facility information by conducting a personal visit interview with a group quarters contact. During this interview, the Census Bureau obtains roster of residents and randomly selects them for person-level interviews. During the person-level phase, a field representative uses a computer-assisted personal interviewing instrument to collect detailed information for each sampled resident. Field representatives also have the option to distribute a bilingual (English/Spanish) questionnaire to residents for self-response if unable to complete a computer-assisted personal interviewing interview. Beginning in 2024, residents in some group quarters will have the option to self-respond to the survey online. A small sample of respondents are recontacted for quality assurance purposes.

Affected Public: Individuals or households.

Frequency: Monthly.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. 141 and 193, and 221.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0810.

Sheleen Dumas,

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

[FR Doc. 2023–04952 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–19–2023]

Foreign-Trade Zone (FTZ) 138, Notification of Proposed Production Activity; Intel Corporation; (Semiconductor Products); New Albany, Ohio

Intel Corporation submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in New Albany, Ohio, within Subzone 138I. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on March 2, 2023.

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

The proposed finished products include semiconductor transducers, electronic integrated circuit processors and amplifiers, electronic memory circuits, and electronic integrated circuits (duty rates are duty-free).

The proposed foreign-status materials and components include: methane (liquid; gas); chlorine; oxygen; hydrogen; helium; xenon; nitrogen; hydrochloric acid; hydrogen chloride; nitric acid; phosphoric acid; phosphoric acid based solution; hydrofluoric acid (also known as hydrogen fluoride); silicate reagent; hydrogen bromide; carbon dioxide; silica; carbon monoxide; dinitrogen monoxide (also known as nitrous oxide); nitric oxide; sulfur dioxide; boron trichloride; dichlorosilane; silane; silicon tetrachloride; chlorine trifluoride; diiodosilane; nitrogen trifluoride; anhydrous ammonia; ammonia; potassium hydroxide; potassium hydroxide based slurry; sulfur hexafluoride gas; tungsten hexafluoride; potassium hydroxide based slurry; sulfur hexafluoride gas; tungsten hexafluoride; titanium tetrachloride; carbonyl sulfide; copper sulphate solution; potassium chloride electrode filling solution; cerium hydroxide based slurry; hydrogen peroxide; disilane; n-octane; ethyne (also known as acetylene); hydrocarbon solution; trifluoromethane; tetrafluoromethane (also known as perfluoromethane); hexafluoro-1,3-butadiene; octafluorocyclobutane; isopropyl alcohol; tert-butyl alcohol; hexachlorodisilane; 2-heptanone; cyclohexanone; cyclopentanone; butyl acetate; propylene glycol monomethyl ether acetate (PGMEA); pentakis(dimethylamido)tantalum powder; tetrakis(methylethylamino)zirconium; N-methylethanolamine solution; tetramethylammonium hydroxide developer solution; bis(diethylamino)silane; hexamethyldisilazane photoresist; N,N-bis(1-methylethyl)silanamine; tetramethylsilane; trimethylaluminum; trimethylsilane; butyrolactone; potassium chloride based solution; methyl 2-hydroxyisobutyrate based photoresist solution; PGMEA based photoresist solution; PGMEA based undercoat material; polyglycerol polymer based slurry; surfactant solution; butoxyethanol based wafer cleaning solution; ethanolamine based wafer cleaning solution; 1-hydroxyethane-1,1-diphosphonic acid based wafer cleaning solution; bolt release lubrication; acetic acid based slurry; ammonium hydroxide based slurry; amorphous silica based slurry; cerium dioxide based slurry; potassium hydroxide based slurry; silica based slurry; tetraethylammonium hydroxide based slurry; silica and phosphoric acid based slurry; various mixtures (photoresist chemicals; diborane and argon; diborane and hydrogen; fluorine

and nitrogen; helium and nitrogen; helium based compressed gas; hydrogen and argon; hydrogen and helium; hydrogen and nitrogen; methane and argon; oxygen and helium; xenon and hydrogen); soldering, brazing, or welding powder; triethanolamine based solution; dimethyl sulfoxide based cleaning solvent; propylene glycol monomethyl ether based solvent; tetramethylammonium hydroxide based cleaning solvent; semi-processed semiconductor wafers; 4-morpholinecarbaldehyde based solution; acetic acid based solution; ammonium fluoride based solution; benzotriazole based cleaning solution; cobalt based solution; ethylene glycol based solution; isobutyl propionate based developer solution; nitric acid based solution; phosphoric acid based solution; tetrahydrothiophene-1,1-dioxide based solution; anti-reflective photoresist chemical coating; melamine resin; ion exchangers; plastic components (cases; packing; bottles); ethylene bags; self-adhesive labels; quartz reactor tubes; copper anode discs; filtering machinery for liquids; permanent metal magnets; central processing units; microprocessors; electronic memory circuits; sputtering targets (cobalt; copper; tantalum; titanium); electrical conductors for a voltage not exceeding 1,000 V (fitted with connectors and used in telecommunication; not used in telecommunication); electrical conductors for a voltage not exceeding 80 V; insulated electrical conductors for a voltage not exceeding 1,000 V; copper electrical conductors for a voltage not exceeding 80 V; fitted electrical conductors for a voltage exceeding 1,000 V; and, electrical conductors for a voltage exceeding 1,000 V (duty rate ranges from duty-free to 6.5%). The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962 (section 232) or section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 232 and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is April 19, 2023.

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

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

Dated: March 7, 2023.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2023–04964 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–18–2023]

Foreign-Trade Zone (FTZ) 3, Notification of Proposed Production Activity; Phillips 66 Company; (Renewable Fuels and By-Products); Rodeo, California

Phillips 66 Company submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Rodeo, California within Subzone 3E. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on March 3, 2023.

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

The proposed finished products include treated renewable feedstock, sulfur, renewable fuels (naphtha; diesel; jet), sustainable jet fuel, butane, and mixed gas streams (duty rate ranges from duty-free to 8.0%, and 10.5¢/bbl).

The proposed foreign-status materials and components include: animal fats; oils (soybean; canola; rapeseed; distiller's corn; used cooking); mixed fats, oils, and grease (also known as FOG); and, greases (trap; brown; yellow (a mix of animal fats that may include used cooking oil)) (duty rate ranges from 0.43¢/kg to 3¢/kg, 3.4% to 19.1%). The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is April 19, 2023.

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

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

Dated: March 6, 2023.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2023–04891 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials and Equipment Technical Advisory Committee; Notice of Open Meeting

The Materials and Equipment Technical Advisory Committee will meet on March 30, 2023, 10 a.m., Eastern Daylight Time. The meeting will be virtual. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction by BIS Senior Management.

2. Report from working groups.

3. Report by regime representatives.

To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than March 23, 2023.

To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

For more information, contact Ms. Springer via email.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2023–04947 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–826]

Certain Hot-Rolled Steel Flat Products From the Republic of Turkey: Final Results of Antidumping Duty Administrative Review; 2020–2021

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas) did not make sales of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Turkey (Turkey) at less than normal value during the period of review (POR), October 1, 2020, through September 30, 2021.

DATES: Applicable March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Lingjun Wang, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2316.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2022, Commerce published the *Preliminary Results* and invited interested parties to comment.[1] No interested party submitted comments on the *Preliminary Results*. Accordingly, the final results remain unchanged from the *Preliminary Results*. Commerce conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [2]

The merchandise covered by the *Order* is certain hot-rolled steel flat products. For a complete description of the scope of the *Order, see* the *Preliminary Results*.

Final Results of Review

We determine the following weighted-average dumping margin exists for the respondent for the POR, October 1, 2020, through September 30, 2021:

Producer or exporter	Weighted-average dumping margin (percent)
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S	0.00

Disclosure

Because Commerce received no comments on the *Preliminary Results,* we have not modified our analysis and no decision memorandum accompanies this **Federal Register** notice. We are adopting the *Preliminary Results* as the final results of this review. Consequently, there are no new calculations to disclose in accordance with section 751(a) of the Act and 19 CFR 351.224(b) for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Because Habas' weighted-average dumping margin is zero percent, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

In accordance with Commerce's practice, for entries of subject merchandise during the POR produced by Habas for which it did not know that its merchandise was destined for the United States, we will instruct CBP to assess antidumping duties for such unexamined entries at the all-others rate (*i.e.,* 2.73 percent) if there is no company-specific rate for the intermediate company(ies) involved in the transaction.[3]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication date 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 deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Habas will be zero; (2) for companies not participating in this review but which were part of a prior segment of this proceeding, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or the underlying investigation, but the producer is, then the cash deposit rate will be the company-specific rate established for the most recently completed segment of the proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 2.73 percent, the all-others rate established in the underlying investigation.[4] 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 the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply

[1] *See Certain Hot-Rolled Steel Flat Products from the Republic of Turkey: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020–2021,* 87 FR 66654 (November 4, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016) (*Order*); *see also Certain Hot-Rolled Steel Flat Products from Turkey: Notice of Court Decision Not in Harmony with the Amended Final Determination in the Less-Than-Fair-Value Investigation; Notice of Amended Final Determination, Amended Antidumping Duty Order, Notice of Revocation of Antidumping Duty Order in Part; and Discontinuation of the 2017–18 and 2018–19 Antidumping Duty Administrative Reviews, in Part,* 85 FR 29399 (May 15, 2020) (*Amended Final Determination*).

[3] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003); *see also Amended Final Determination.*

[4] *See Amended Final Determination.*

with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: March 6, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–04903 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Cancellation of Middle East Clean Tech Executive Led Trade Mission to Saudi Arabia, the UAE, and Israel, March 12–17, 2023

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: On March 18, 2022, the United States Department of Commerce notified the public of Winter 2022 approved International Trade Administration Missions (87 FR 15374, Mar. 18, 2022), including a Middle East Clean Tech Executive Led Trade Mission to Saudi Arabia, the UAE, and Israel, March 12–17, 2023. The International Trade Administration has cancelled this Trade Mission.

Cancellation Notice

In the **Federal Register** Notice of March 18, 2022, 87 FR 15374 on page 15374, title note at top of page, correct the subject heading of the notice to read: Announcement of Winter 2022 Approved International Trade, Middle East Executive-led Clean Tech Trade Mission to Saudi Arabia, the UAE, and Israel, has been cancelled, 3/12–3/17/2023.

FOR FURTHER INFORMATION CONTACT: Larry Tabash, Global Middle East & Africa Team Lead, U.S. Commercial Service, Arlington, VA, (512) 936–0039, *larry.tabash@trade.gov.*

Gemal Brangman,

Director, ITA Events Management Task Force.

[FR Doc. 2023–04983 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Court Decision Not in Harmony With the Results of Antidumping Administrative Review; Notice of Amended Final Results; Correction

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

ACTION: Notice; correction.

SUMMARY: The Department of Commerce (Commerce) published a notice in the **Federal Register**, in which it amended the final results of the 2017–2018 administrative review of the antidumping duty order on crystalline silicon photovoltaic cells, whether or not assembled into modules, (solar cells and modules) from the People's Republic of China (China) pursuant to a final judgment by the U.S. Court of International Trade (CIT). That notice contains incorrect weighted-average dumping margins for two company groupings.

FOR FURTHER INFORMATION CONTACT: Paola Aleman Ordaz, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4031.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of January 5, 2023, in FR Doc 2023–856, on page 857, correct the weighted-average dumping margins listed within the weighted-average dumping margins table for the below company groupings, as follows:

Exporters	Amended weighted-average dumping margins (percent)
Trina Solar Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yancheng Trina Guoneng Photovoltaic Technology Co., Ltd./Changzhou Trina Solar Yabang Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd./Trina Solar (Hefei) Science and Technology Co., Ltd./Changzhou Trina Hezhong Photoelectric Co., Ltd	25.18
Risen Energy Co. Ltd./Risen (Wuhai) New Energy Co., Ltd./Zhejiang Twinsel Electronic Technology Co., Ltd./Risen (Luoyang) New Energy Co., Ltd./Jiujiang Shengchao Xinye Technology Co., Ltd./Jiujiang Shengzhao Xinye Trade Co., Ltd./Ruichang Branch, Risen Energy (HongKong) Co., Ltd./Risen Energy (Changzhou) Co., Ltd	19.20

Background

On January 5, 2023, Commerce published in the **Federal Register** a notice of amended final results of the 2017–2018 administrative review of the antidumping duty order on solar cells and modules from China pursuant to a final judgment by the CIT.[1] In that *Amended Final/Timken,* we listed incorrect weighted-average dumping margins in the amended final results table for the company groupings identified above.

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.

Dated: March 6, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–04962 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Notice of Court Decision Not in Harmony With the Results of Antidumping Administrative Review; Notice of Amended Final Results,* 88 FR 856 (January 5, 2023) (*Amended Final/Timken*).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–833]

Utility Scale Wind Towers From Indonesia: Final Results of Antidumping Duty Administrative Review; 2020–2021

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

SUMMARY: The Department of Commerce (Commerce) determines that PT. Kenertec Power System made sales of subject merchandise at less than normal value during the period of review (POR), February 14, 2020, through July 31, 2021.

DATES: Applicable March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Luberda, 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.

SUPPLEMENTARY INFORMATION:

Background

This review covers a single producer and exporter of the subject merchandise, PT. Kenertec Power System (Kenertec). Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). On September 6, 2022, Commerce published the *Preliminary Results.*[1] On December 16, 2022, we postponed the final results until March 3, 2023.[2] 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 in case briefs for these final results, may be found in the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *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.*

Scope of the Order[4]

The merchandise subject to the *Order* is certain wind towers, whether or not tapered, and sections thereof, from Indonesia. Merchandise covered by these orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 7308.20.0020 or 8502.31.0000. Wind towers of iron or steel are classified under HTSUS 7308.20.0020 when imported separately as a tower or tower section(s). Wind towers may be classified under HTSUS 8502.31.0000 when imported as combination goods with a wind turbine (*i.e.,* accompanying nacelles and/or rotor blades). While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these orders is dispositive.[5]

Analysis of Comments Received

All issues raised in case and rebuttal briefs 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 dumping margin calculated for Kenertec.[6]

Final Results of the Review

We have calculated the following weighted-average dumping margin for Kenertec for the period February 14, 2020, through July 31, 2021:

Exporter or producer	Weighted-average dumping margin (percent)
PT. Kenertec Power System	2.03

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to the interested 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), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), where Kenertec reported the entered value of its 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. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[7]

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by Kenertec for which Kenertec did not know that the merchandise it 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 such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[8]

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

[1] *See Utility Scale Wind Towers from Indonesia: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021,* 87 FR 54478 (September 6, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Utility Scale Wind Towers from Indonesia: Extension of Deadline for Final Results of 2020–2021 Antidumping Duty Administrative Review,'' dated December 16, 2022.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2020–2021 Administrative Review of the Antidumping Duty Order on Utility Scale Wind Towers from Indonesia,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 85 FR 52546 (August 26, 2020) (*Order*), corrected in *Utility Scale Wind Towers from Canada, Indonesia, the Republic of Korea, and the Socialist Republic of Vietnam: Notice of Correction to the Antidumping Duty Orders,* 85 FR 56213 (September 11, 2020).

[5] For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum at 2–3.

[6] *See* accompanying Issues and Decision Memorandum.

[7] *See* section 751(a)(2)(C) of the Act.

[8] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

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 Kenertec will be will be 2.03 percent; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company was reviewed or investigated; (3) if the exporter is not a firm covered in this review, a previous review, or the LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 8.53 percent, the all-others rate from the original investigation.[9]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this 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 the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: March 3, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Changes to the Margin Calculations
V. Discussion of the Issues
  Comment 1: Purchases of Marine Insurance from an Affiliated Party
  Comment 2: Constructed Value (CV) Profit and Selling Expenses
  Comment 3: Rejection of Certain CV Profit Information
  Comment 4: Kenertec's Control Numbers to Account for Different Theoretical Weights for the Same Product
  Comment 5: Domestic Brokerage and Handling Adjustment to Kenertec's U.S. Gross Unit Price
  Comment 6: Appropriate U.S. Quantity Variable for the Margin Calculations
  Comment 7: Treatment of Reimbursement for Certain Movement Expenses
  Comment 8: Whether Commerce Should Treat Certain Expenses as Movement Expenses
  Comment 9: Basis for Kenertec's U.S. and Home Market Warranty Expense
VI. Recommendation

[FR Doc. 2023–04902 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See Utility Scale Wind Towers from Indonesia: Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances,* 85 FR 40231, 40232 (July 6, 2020).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC830]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public webinar of its Scallop 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 meeting will be held on Wednesday, March 29, 2023, at 9 a.m.

ADDRESSES:

Webinar registration URL information: https://attendee.gotowebinar.com/register/6942446589461298268.

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 Committee will review the 2023 Scallop Work Priorities, including a work plan for this calendar year. They also plan to review and recommend revisions, if necessary, to the draft goals and objectives for the Northern Edge Habitat/Scallop Management Framework. The draft goals and objectives will be discussed by the Habitat Committee on March 23, 2023. Also on the agenda is a discussion of potential modifications to the RSA program as recommended by the RSA Program Review and Sea Scallop Survey Working Group. The Committee plans to discuss the Scallop RSA Priorities and begin identifying possible focus areas for 2024/25. Other business will be discussed, if necessary.

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: March 7, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–04943 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC832]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of hybrid meeting open to the public offering both in-person and virtual options for participation.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a four-day meeting to consider actions affecting the Gulf of Mexico fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will convene Monday, April 3 through Thursday, April 6, 2023, from 8 a.m. to 5 p.m., CDT.

ADDRESSES: *Meeting address:* The meeting will take place at the Courtyard Marriott Gulfport Beachfront hotel, located at 1600 East Beach Boulevard, Gulfport, MS 39501.

Please note, in-person meeting attendees will be expected to follow any current safety protocols as determined by the Council, hotel and the City of Gulfport, if any. Such precautions may include masks, room capacity restrictions, and/or social distancing. If you prefer to ''listen in'', you may access the log-on information by visiting our website at *www.gulfcouncil.org.*

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Monday, April 3, 2023; 8 a.m.–5 p.m., CDT

The meeting will begin in a CLOSED SESSION of the FULL COUNCIL to review and select *Coastal Migratory Pelagic* (CMP) Advisory Panel (AP) members, 2022 Law Enforcement Officer/Team of the Year, and consider the replacement of a member for the Standing Scientific and Statistical Committee. At approximately 9 a.m. the meeting will open to the public with the *Mackerel* Committee reviewing the CMP Landings, Final Action: Draft Framework Amendment 12: Modifications to the Gulf of Mexico Migratory Group King *Mackerel* Gillnet Fishing Season and recommendations from the CMP AP December 2022 meeting.

The Data Collection Committee will receive an update on Southeast For-Hire Integrated Reporting (SEFHIER) Program: Discussion on 5th Circuit Court of Appeals Ruling and Regulatory Next Steps, Modification to Commercial Coastal Logbook Reporting Requirements, discussion on Private Angler Licensing Requirements and the Feasibility of a Federal Private Angling Permit Initiatives for federal private recreational management and any remaining Data Collection AP Summary items from the February 13, 2023 meeting.

Following lunch, the *Shrimp* Committee will convene to review and discuss the Biological Review of Texas Closure, Updates on NMFS VMS Pilot Project on *Shrimp* Vessels, Report on Expanded Sampling of the Fleet for Effort Monitoring in the Gulf *Shrimp* Fishery, and the Draft *Shrimp* Framework Action: Modification of the Vessel Position Data Collection Program for the Gulf of Mexico *Shrimp* Fishery. The Committee will receive an Update on *Shrimp* Effort Estimation Model and 2021 Gulf *Shrimp* Fishery Effort, *Shrimp* Advisory Panel Summary Reports, and Scientific and Statistical Committee Summary Report from the March 2023 meetings.

The *Reef Fish* Committee will convene and review Recent *Reef Fish,* For-hire, and Individual Fishing Quota Landings.

Tuesday, April 4, 2023; 8 a.m.–5 p.m., CDT

The *Reef Fish* Committee will reconvene to review and discuss Public Hearing Draft for Amendment 56: Modifications to the *Gag Grouper* Catch Limits, Sector Allocations, and Fishing Seasons, Draft Framework: Modifications to Recreational and Commercial *Greater Amberjack* Management Measures, and Discussion of Individual Fishing Quota (IFQ) Objectives.

Reef Fish Committee will review the SSC Summary Report and Recommendations from the March 2023 Meeting; *Scamp* and *Yellowmouth Grouper* Updated Catch Projections; Evaluating Bottom Fishing Seasonal Closures in the Recreational Fishery; *Greater Amberjack* Discard Mortality; *Greater Amberjack* Count Update; Evaluating Wenchman and Mid-water Snapper Landings; and, Other Items from March 2023 SSC Meeting. The Committee will discuss and review Draft Options: Updating Recreational *Red Snapper* Calibration Ratios and Establishing *Gray Snapper* Catch Limits.

Immediately following the Reef Fish Committee, National Marine Fisheries Service Staff will host a General Question and Answer Session.

Wednesday, April 5, 2023; 8 a.m.–5 p.m., CDT

The Sustainable Fisheries Committee will receive a presentation on A Brief Introduction to how Management Strategy Evaluation can Address Some Key Challenges before the Council; receive an overview of Potential Options for Regulatory Streamlining; a presentation on Factors to Consider for the Inclusion of Species in Federal Management; and, a presentation SSC Report on Allocation Approaches.

At approximately 11:15 a.m., CDT, the Council will convene with a Call to Order, Announcements and Introductions, Adoption of Agenda and Approval of Minutes. The Council will receive updates from the Bureau of Ocean Energy Management (BEOM) on Wind Energy Development in the Gulf of Mexico and NOAA Fisheries' Equity and Environmental Justice (EEJ) Strategy, Regional Implementation Process, and Schedule.

The Council will hold public testimony from 1:30 p.m. to 5 p.m., CDT on Final Action: Draft Framework Amendment 12: Modifications to the Gulf of Mexico Migratory Group *King Mackerel* Gillnet Fishing Season; and, open testimony on other fishery issues or concerns. Public comment may begin earlier than 1:30 p.m. CDT, but will not conclude before that time. Persons wishing to give public testimony in-person must register at the registration kiosk in the meeting room. Persons wishing to give public testimony virtually must sign up via the link on the Council website. Registration for virtual testimony is open at the start of the meeting, Monday, April 3rd at 8 a.m., CDT and closes one hour before public testimony begins on Wednesday, April 5th at 12:30 p.m., CDT.

Thursday, April 6, 2023; 8 a.m.–5 p.m., CDT

The Council will receive Committee reports from *Mackerel,* Data Collection, *Shrimp, Reef Fish,* Sustainable Fisheries Management Committees as well as the

closed session report the Council will receive updates from the following supporting agencies: South Atlantic Fishery Management Council; Mississippi Law Enforcement Efforts; NOAA Office of Law Enforcement (OLE); Gulf States Marine Fisheries Commission; U.S. Coast Guard; U.S. Fish and Wildlife Service; and Department of State.

The Council will discuss any Other Business items; and, Litigation update.

—Meeting Adjourns

The meeting will be a hybrid meeting; both in-person and virtual participation available. You may register for the webinar to listen-in only by visiting *www.gulfcouncil.org* and click on the Council meeting on the calendar.

The timing and order in which agenda items are addressed may change as required to effectively address the issue, and the latest version along with other meeting materials will be posted on the website as they become available.

Although other non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meeting. Actions 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 that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira, (813) 348–1630, at least 15 days prior to the meeting date.

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

Dated: March 7, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–04944 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC829]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public webinar of its Scallop Advisory Panel 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, March 28, 2023, at 9 a.m.

ADDRESSES: Webinar registration URL information: *https://attendee.gotowebinar.com/register/2214017724931485789*.

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 Advisory Panel will review the 2023 Scallop Work Priorities, including a work plan for this calendar year. They also plan to review and recommend revisions, if necessary, to the draft goals and objectives for the Northern Edge Habitat/Scallop Management Framework. The draft goals and objectives will be discussed by the Habitat Committee on March 23, 2023. Also on the agenda is a discussion of potential modifications to the RSA program as recommended by the RSA Program Review and Sea Scallop Survey Working Group. The Advisory Panel plans to discuss the Scallop RSA Priorities and begin identifying possible focus areas for 2024/25. Other business will be discussed, if necessary.

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: March 7, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–04942 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC801]

Pacific Bluefin Tuna United States Stakeholder Meeting; Meeting Announcement

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

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a public meeting to discuss development of a long-term harvest strategy for Pacific bluefin tuna (PBF). This meeting is intended to prepare for potential discussions at the 2023 meeting of the Joint Inter-American Tropical Tuna Commission (IATTC)—Western and Central Pacific Fisheries Commission (WCPFC) Northern Committee (NC) Working Group on a long-term harvest strategy for PBF fisheries across the Pacific Ocean. The meeting topics are described under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The virtual meeting will be held on April 19, 2023, from 1 p.m. to 4 p.m. Pacific Daylight Time (or until business is concluded). You must complete the registration process by April 12, 2023, if you plan to attend the meeting (see **ADDRESSES**). Members of the public may submit written comments on meeting topics or materials to Celia Barroso at *celia.barroso@noaa.gov* by April 12,

2023, and may also provide oral comments during the virtual meeting.

ADDRESSES: If you plan to attend the meeting, which will be held by webinar, please register at *https://forms.gle/rVj5WNy4w4Kadqcq6.* Instructions for attending the meeting will be emailed to meeting participants before the meeting occurs. This meeting may be audio recorded for the purposes of generating notes of the meeting. As public comments will be made publicly available, participants and public commenters are urged not to provide personally identifiable information (PII) at this meeting. Participation in the meeting, in person, by web conference, or by telephone constitutes consent to the audio recording.

FOR FURTHER INFORMATION CONTACT: Celia Barroso, NMFS West Coast Region, 562–432–1850, *celia.barroso@noaa.gov.*

SUPPLEMENTARY INFORMATION: The 7th Meeting of the Joint IATTC–WCPFC NC Working Group (JWG) met July 12–14, 2022, and was unable to reach consensus on management objectives for PBF and metrics to measure whether a proposed harvest strategy would meet those management objectives. Additionally, the International Scientific Committee on Tuna and Tuna-like Species in the North Pacific Ocean (ISC) recommended that, to proceed with the development of a management strategy evaluation (MSE) for PBF, the JWG consider refining the set of candidate reference points and harvest control rules recommended in 2019. This April 19 meeting is being held to prepare for anticipated discussions at the 2023 meeting of the JWG regarding scenarios for evaluation in the MSE to support development of potential harvest strategies for PBF. This is expected to include the objectives and metrics to evaluate the effectiveness of those scenarios.

PBF U.S. Stakeholder Meeting Topic

The agenda for this meeting will be distributed to participants in advance of the meeting. The meeting agenda will include a discussion on preferences for management objectives for PBF, metrics to measure how potential future harvest strategies for PBF meet those objectives, candidate reference points, and candidate harvest control rules.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be indicated when registering for the meeting (see **ADDRESSES**) by April 12, 2023.

Authority: 16 U.S.C. 951 *et seq.;* 16 U.S.C. 1801 *et seq.;* and 16 U.S.C. 6901 *et seq.*

Dated: March 7, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–04925 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC833]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Pacific Northwest Crab Industry Advisory Committee (PNCIAC) will meet March 29, 2023.

DATES: The meeting will be held on Wednesday, March 29, 2023, from 1 p.m. to 2 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2987.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Sarah Marrinan, Council staff; phone; (907) 271–2809; email: *sarah.marrinan@noaa.gov.* For technical support, please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Wednesday, March 29, 2023

The Committee will (a) conduct election of officers (b) discuss pending Council crab actions for June; (c) discuss upcoming Crab Rationalization Program Review; and (d) other business. The agenda is subject to change, and the latest version will be posted *https://meetings.npfmc.org/Meeting/Details/2987* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone, or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2987.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2987.*

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

Dated: March 7, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–04945 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC826]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice of issuance of Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that a Letter of Authorization (LOA) has been issued to Shell Offshore Inc. (Shell) for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico.

DATES: The LOA is effective from March 7, 2023, through March 31, 2024.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322, January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

Shell plans to conduct a 3D ocean bottom node (OBN) survey in Stones Lease Block WR 508 and the surrounding approximately 100 lease blocks, with approximate water depths ranging from 1,825 to 3,050 meters (m). See Section F of the LOA application for a map of the area. Shell anticipates using a single source vessel, towing a conventional airgun array source consisting of 32 elements, with a total volume of 5,110 cubic inches (in ^{3}). Please see Shell's application for additional detail.

Consistent with the preamble to the final rule, the survey effort proposed by Shell in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (86 FR 5398, January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) survey type; (2) location (by modeling zone [1]); (3) number of days; and (4) season.[2] The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

No 3D OBN surveys were included in the modeled survey types, and use of existing proxies (*i.e.,* 2D, 3D NAZ, 3D WAZ, Coil) is generally conservative for use in evaluation of 3D OBN survey effort, largely due to the greater area covered by the modeled proxies. Summary descriptions of these modeled survey geometries are available in the preamble to the proposed rule (83 FR 29212, 29220, June 22, 2018). Coil was selected as the best available proxy survey type because the spatial coverage of the planned survey is most similar to that associated with the coil survey pattern. The planned 3D OBN survey will involve one source vessel sailing along closely spaced survey lines approximately 30 km in length. The coil survey pattern in the model was assumed to cover approximately 144 kilometers squared (km^2) per day (compared with approximately 795 km^2, 199 km^2, and 845 km^2 per day for the 2D, 3D NAZ, and 3D WAZ survey patterns, respectively). Among the different parameters of the modeled survey patterns (*e.g.,* area covered, line spacing, number of sources, shot interval, total simulated pulses), NMFS considers area covered per day to be most influential on daily modeled exposures exceeding Level B harassment criteria. Although Shell is not proposing to perform a survey using the coil geometry, its planned 3D OBN survey is expected to cover approximately 15 km^2 per day, meaning that the coil proxy is most representative of the effort planned by Shell in terms of predicted Level B harassment exposures.

In addition, all available acoustic exposure modeling results assume use of a 72-element, 8,000 in^3 array. Thus, take numbers authorized through the LOA are considered conservative due to differences in both the airgun array (32 elements, 5,110 in^3) and the daily survey area planned by Shell (15 km^2), as compared to those modeled for the rule.

The survey is planned to occur for approximately 70 days in Zone 7, with airguns being used on 55 of the days. The seasonal distribution of survey days is not known in advance. Therefore, the take estimates for each species are based on the season that has the greater value for the species (*i.e.,* winter or summer).

For some species, take estimates based solely on the modeling yielded results that are not realistically likely to occur when considered in light of other relevant information available during the rulemaking process regarding marine mammal occurrence in the GOM. The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each

[1] For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

[2] For purposes of acoustic exposure modeling, seasons include Winter (December–March) and Summer (April–November).

modeling zone. Thus, although the modeling conducted for the rule is a natural starting point for estimating take, the rule acknowledged that other information could be considered (see, *e.g.,* 86 FR 5442 (January 19, 2021), discussing the need to provide flexibility and make efficient use of previous public and agency review of other information and identifying that additional public review is not necessary unless the model or inputs used differ substantively from those that were previously reviewed by NMFS and the public). For this survey, NMFS has other relevant information reviewed during the rulemaking that indicates use of the acoustic exposure modeling to generate a take estimate for certain marine mammal species produces results inconsistent with what is known regarding their occurrence in the GOM. Accordingly, we have adjusted the calculated take estimates for the species as described below.

Killer whales are the most rarely encountered species in the GOM, typically in deep waters of the central GOM (Roberts *et al.,* 2015; Maze-Foley and Mullin, 2006). The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. NMFS has determined that the approach results in unrealistic projections regarding the likelihood of encountering killer whales.

As discussed in the final rule, the density models produced by Roberts *et al.* (2016) provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. GOM. The predictions represent the output of models derived from multi-year observations and associated environmental parameters that incorporate corrections for detection bias. However, in the case of killer whales, the model is informed by few data, as indicated by the coefficient of variation associated with the abundance predicted by the model (0.41, the second-highest of any GOM species model; Roberts *et al.,* 2016). The model's authors noted the expected non-uniform distribution of this rarely-encountered species (as discussed above) and expressed that, due to the limited data available to inform the model, it ''should be viewed cautiously'' (Roberts *et al.,* 2015).

NOAA surveys in the GOM from 1992–2009 reported only 16 sightings of killer whales, with an additional 3 encounters during more recent survey effort from 2017–18 (Waring *et al.,* 2013; *www.boem.gov/gommapps*). Two other species were also observed on fewer than 20 occasions during the 1992–2009 NOAA surveys (Fraser's dolphin and false killer whale [3]). However, observational data collected by protected species observers (PSOs) on industry geophysical survey vessels from 2002–2015 distinguish the killer whale in terms of rarity. During this period, killer whales were encountered on only 10 occasions, whereas the next most rarely encountered species (Fraser's dolphin) was recorded on 69 occasions (Barkaszi and Kelly, 2019). The false killer whale and pygmy killer whale were the next most rarely encountered species, with 110 records each. The killer whale was the species with the lowest detection frequency during each period over which PSO data were synthesized (2002–2008 and 2009–2015). This information qualitatively informed our rulemaking process, as discussed at 86 FR 5334 (January 19, 2021), and similarly informs our analysis here.

The rarity of encounter during seismic surveys is not likely to be the product of high bias on the probability of detection. Unlike certain cryptic species with high detection bias, such as *Kogia* spp. or beaked whales, or deep-diving species with high availability bias, such as beaked whales or sperm whales, killer whales are typically available for detection when present and are easily observed. Roberts *et al.* (2015) stated that availability is not a major factor affecting detectability of killer whales from shipboard surveys, as they are not a particularly long-diving species. Baird *et al.* (2005) reported that mean dive durations for 41 fish-eating killer whales for dives greater than or equal to 1 minute in duration was 2.3–2.4 minutes, and Hooker *et al.* (2012) reported that killer whales spent 78 percent of their time at depths between 0–10 m. Similarly, Kvadsheim *et al.* (2012) reported data from a study of four killer whales, noting that the whales performed 20 times as many dives 1–30 m in depth than to deeper waters, with an average depth during those most common dives of approximately 3 m.

In summary, killer whales are the most rarely encountered species in the GOM and typically occur only in particularly deep water. While this information is reflected through the density model informing the acoustic exposure modeling results, there is relatively high uncertainty associated with the model for this species, and the acoustic exposure modeling applies mean distribution data over areas where the species is in fact less likely to occur. NMFS' determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for killer whales will generally result in estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected killer whale take (86 FR 5403, January 19, 2021).

In past authorizations, NMFS has often addressed situations involving the low likelihood of encountering a rare species such as killer whales in the GOM through authorization of take of a single group of average size (*i.e.,* representing a single potential encounter). See 83 FR 63268, December 7, 2018. See also 86 FR 29090, May 28, 2021 and 85 FR 55645, September 9, 2020. For the reasons expressed above, NMFS determined that a single encounter of killer whales is more likely than the model-generated estimates and has authorized take associated with a single group encounter (*i.e.,* up to 7 animals).

Based on the results of our analysis, NMFS has determined that the level of taking expected for this survey and authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See table 1 in this notice and table 9 of the rule (86 FR 5322, January 19, 2021).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed ''small numbers.'' In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS' discussion of the MMPA's small numbers requirement provided in the final rule (86 FR 5438, January 19, 2021).

The take numbers for authorization are determined as described above in the Summary of Request and Analysis section. Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the

[3] However, note that these species have been observed over a greater range of water depths in the GOM than have killer whales.

likelihood that some individual marine mammals may be taken on more than one day (see 86 FR 5404, January 19, 2021). The output of this scaling, where appropriate, is incorporated into adjusted total take estimates that are the basis for NMFS' small numbers determinations, as depicted in table 1.

This product is used by NMFS in making the necessary small numbers determinations through comparison with the best available abundance estimates (see discussion at 86 FR 5391, January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock assessment reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and model-predicted abundance information (*https://seamap.env.duke.edu/models/Duke/GOM/*). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.,* 3-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in table 1.

TABLE 1—TAKE ANALYSIS

Species	Authorized take	Scaled take [1]	Abundance [2]	Percent abundance
Rice's whale [3]	0	n/a	51	n/a
Sperm whale	291	123.2	2,207	5.6
Kogia spp.	[4] 164	48.2	4,373	1.4
Beaked whales	2,572	259.8	3,768	6.9
Rough-toothed dolphin	478	137.2	4,853	2.8
Bottlenose dolphin	[5] 21	6.0	176,108	0.0
Clymene dolphin	1,262	362.1	11,895	3.0
Atlantic spotted dolphin	0	n/a	74,785	n/a
Pantropical spotted dolphin	12,526	3,595.0	102,361	3.5
Spinner dolphin	294	84.4	25,114	0.3
Striped dolphin	655	188.1	5,229	3.6
Fraser's dolphin	206	59.2	1,665	3.6
Risso's dolphin	203	60.0	3,764	1.6
Melon-headed whale	813	239.9	7,003	3.4
Pygmy killer whale	396	116.7	2,126	5.5
False killer whale	448	132.1	3,204	4.1
Killer whale	7	n/a	267	2.6
Short-finned pilot whale	64	19.0	1,981	1.0

[1] Scalar ratios were applied to "Authorized Take" values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.

[2] Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For Rice's whale and killer whale, the larger estimated SAR abundance estimate is used.

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

[4] Includes 14 takes by Level A harassment and 150 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

[5] Modeled take of 13 increased to account for potential encounter with group of average size (Maze-Foley and Mullin, 2006).

Based on the analysis contained herein of Shell's proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes (*i.e.,* less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to Shell authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: March 7, 2023.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–04949 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability of a Final Management Plan and Final Environmental Assessment for the Channel Islands National Marine Sanctuary

AGENCY: Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of availability.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) has prepared a final management plan (FMP) as part of the Channel Islands National Marine Sanctuary (CINMS or sanctuary) management plan review. The FMP, which replaces a 2009 sanctuary management plan, addresses current and emerging threats in CINMS and reflects changes in new science and technologies, how the public uses the sanctuary, and community needs. The FMP supports continued protection of sanctuary resources through enforcement of existing sanctuary regulations, education and outreach strategies that promote ocean stewardship, and community-inclusive involvement. Consistent with the

information provided in the 2019 Notice of Intent, and information gathered through public scoping to prepare a draft environmental assessment (DEA) and draft management plan (DMP) for the sanctuary, and public comments received on the DMP, NOAA is not making modifications to the sanctuary regulations at this time, but may consider regulatory changes in the future. NOAA also prepared a final environmental assessment (FEA) and a finding of no significant impact (FONSI) for this action.

DATES: The final management plan and environmental assessment for Channel Islands National Marine Sanctuary is now available.

ADDRESSES: The FMP, FEA, and FONSI are available at *https://channelislands.noaa.gov/manage/plan/.* The DMP is available at *https://nmschannelislands.blob.core.windows.net/channelislands-prod/media/docs/2021-cinms-draft-management-plan.pdf,* and the DEA is available at *https://nmschannelislands.blob.core.windows.net/channelislands-prod/media/docs/2021-cinms-draft-environmental-assessment.pdf.* All comments on the DMP and DEA can be viewed via the Federal eRulemaking Portal: go to *https://www.regulations.gov* and enter ''NOAA–NOS–2019–0110'' in the Search box.

FOR FURTHER INFORMATION CONTACT: Michael Murray, Deputy Superintendent for Programs, Channel Islands National Marine Sanctuary, 805–893–6418, *cinmsmanagement plan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Channel Islands National Marine Sanctuary surrounds five of the eight Channel Islands: San Miguel, Santa Rosa, Santa Cruz, Anacapa, and Santa Barbara off the coast of California. The sanctuary consists of an area of approximately 1,110 square nautical miles (nmi^2) (3,807 square kilometers) of coastal and ocean waters extending an average distance of 6 nautical miles (11.1 kilometers) from island shorelines, and at its deepest point, reaches 5,597 feet (1,706 meters). The sanctuary is home to numerous species of marine mammals, seabirds, fishes, invertebrates, and algae in a remarkably productive coastal environment. Within its boundary is a rich array of habitats, from rugged rocky shores and lush kelp forests to deep canyons and seagrass beds. These habitats abound with life, from tiny microscopic plants to enormous blue whales. The islands and surrounding sanctuary waters have been, and remain, sacred to Indigenous Chumash people. In addition, while the offshore location of the sanctuary limits human presence, the area supports a variety of human uses, such as recreation, tourism, commercial fishing, research, and education.

II. Management Plan Review

The purpose of this management plan review is to ensure the sanctuary is fulfilling the purposes and policies outlined in section 301(b) of the National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431(b)), and effectively protecting and managing the resources of the sanctuary. As required by section 304(e) of the NMSA (16 U.S.C. 1434(e)), a management plan review enables NOAA to evaluate the substantive progress toward implementing the sanctuary's existing management plan and the goals for the sanctuary and to revise the sanctuary's management plan and regulations as necessary to fulfill the purposes and policies of the NMSA. A revised sanctuary management plan enables NOAA's Office of National Marine Sanctuaries (ONMS) to adjust the allocation of time and resources to focus on new priority issues, partnerships, technologies and opportunities that have emerged since the existing sanctuary management was published. A revised management plan also prioritizes use of collaborative and community-based approaches to pursuing sanctuary goals, supported by a variety of partnerships with government agencies, scientific entities, tribal communities, non-governmental organizations, and sanctuary volunteers and advisory council members.

Updates to the CINMS management plan are based on ONMS's evaluation, advisory council input on the 2009 management plan, analysis of comments received on the 2019 Notice of Intent, DMP, and DEA, and findings from the latest CINMS condition report. While the condition report, using quantitative data gathered through 2016, found overall that sanctuary resources were doing well in comparison to many other ocean areas, it also highlighted several pressures and activities causing impacts to the sanctuary, such as vessel traffic, introduction of non-native species, ocean noise, marine debris, harmful algal blooms, and climate-driven changes to ocean conditions. The condition report's ecosystem services assessment also provided an important reminder about the unique and profound value of the sanctuary environment to the Indigenous Chumash people.

NOAA received 36 comments (letters and oral testimony) on the DMP and DEA during the December 17, 2021, through February 24, 2022, public review period. Altogether, the comments received contained 159 specific requests and suggestions for consideration. NOAA hosted two virtual public meetings on January 18, and January 27, 2022.

III. Action Plans

The FMP includes 11 action plans covering issue- and program-based themes that are intended to guide sanctuary staff over the coming five to ten years. Across these action plans, ONMS also emphasizes four important cross-cutting themes and approaches: addressing climate change, fostering diversity and inclusion, relying on partnerships and collaborations, and supporting community-based engagement. The following is a list of the 11 action plans:

1. *Climate Change:* Sanctuary waters, as well as surrounding coastal areas and communities, are experiencing climate-related stressors (*e.g.,* ocean acidification, thermal stress, and hypoxia) that will increase in frequency and intensity over the coming decades. This action plan outlines strategies to better understand and mitigate the effects of climate change on sanctuary resources through capacity building and collaborative partnerships.

2. *Marine Debris:* This action plan prioritizes the assessment of marine debris within CINMS and the development of a better understanding of how marine debris affects sanctuary resources. Strategies include sustaining and expanding island shoreline cleanup efforts, pursuing collaborative efforts with the local fishing community, and implementing education and outreach initiatives with partners.

3. *Vessel Traffic:* A wide array of public and private vessels carry visitors and cargo while transiting through the sanctuary year-round. This action plan outlines strategies to facilitate vessel activity while protecting sanctuary resources. Some strategies include engaging boaters and the shipping industry, tracking and monitoring vessel traffic, and enacting policies to foster safe navigation and protect sanctuary resources in coordination with other agencies and partners.

4. *Introduced Species:* Introduced species are an increasingly common global threat, and the rate of invasion of introduced species continues to accelerate. The strategies in this action plan outline efforts to reduce the introduction, spread, and establishment of introduced species, and to track,

study, and, where possible, control populations of introduced species already established in the sanctuary.

5. *Zone Management:* This action plan focuses on implementing effective management and enforcement strategies of existing protective zones established within the sanctuary, including the Channel Islands network of marine reserves and conservation areas designated by NOAA and the State of California.

6. *Education and Outreach:* This action plan seeks to increase appreciation and stewardship of sanctuary resources by building greater public understanding, engagement, and awareness throughout our diverse coastal communities. This action plan also focuses on support for sanctuary recreational activities and tourism.

7. *Research and Monitoring:* To expand our understanding of the sanctuary ecosystems, this action plan outlines five strategies for research and monitoring that are responsive to existing resource protection and management concerns, yet are also forward-looking to support ecosystem-based management decision making, resource protection initiatives, and education and outreach programs.

8. *Resource Protection:* This action plan identifies five strategies to reduce human impacts to marine wildlife and other sanctuary resources. Through collaborative management with local stakeholders and in partnership and consultation with relevant local, State, and Federal government agencies, this action plan seeks to protect the biological, historical, and cultural resources in the sanctuary from known, emerging, and future unknown threats.

9. *Cultural Heritage:* To respectfully honor, celebrate, and protect the unique Indigenous cultural heritage resources connected to the sanctuary, this action plan features strategies and activities that support meaningful Chumash Community collaborations, engagement with Chumash Community partners revitalizing maritime traditions, and appropriate integration of traditional ecological knowledge.

10. *Maritime Heritage:* This action plan describes strategies and activities focused on the understanding, protection, and interpretation of the unique maritime heritage resources and values connected to sanctuary waters.

11. *Operations and Administration:* This action plan addresses the necessary operational and administrative activities required for implementing an effective program, including staffing, infrastructure needs, and operational improvements.

IV. National Environmental Policy Act Compliance

As required under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), NOAA has prepared an FEA to evaluate the potential impacts on the human environment of implementing NOAA's proposed action. With this action, NOAA is updating its management activities conducted within CINMS that relate to research, monitoring, education, outreach, community engagement, and resource protection. The management activities include the revised sanctuary management plan and implementing routine field activities and existing sanctuary regulations. As described in the FEA and FONSI, no significant impacts to resources and the human environment are expected to result from this action. Accordingly, under NEPA, an Environmental Assessment is the appropriate document to analyze the potential impacts of this action. NOAA has also prepared, as an appendix to the FEA, responses to public comments on the draft management plan and draft environmental assessment.

Authority: 16 U.S.C. 1431 *et seq.;* 42 U.S.C. 4321 *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–04973 Filed 3–9–23; 8:45 am]

BILLING CODE 3510–NK–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the procurement list.

SUMMARY: This action adds product(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* April 9, 2023.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 12/3/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product(s) are added to the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8925–01–E62–6898—Syrup, Maple, Imitation, Thick
8925–01–E62–6897—Syrup, Maple, Imitation

Designated Source of Supply: Golden Rule Industries of Muskogee, Inc., Muskogee, OK

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

Mandatory for: 100% of the requirement of the Department of Defense

Deletions

On 12/23/2022 and 1/13/2023, the Committee for Purchase From People Who Are Blind or Severely Disabled

published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
6645–01–584–0892—Clock, Mini Desk, Rosewood
Designated Source of Supply: Tarrant County Association for the Blind, Fort Worth, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Service(s)

Service Type: Food Service Attendant
Mandatory for: US Army, Helemano Military Reservation, Building 300, Wahiawa, HI
Designated Source of Supply: Opportunities and Resources, Inc., Wahiawa, HI
Contracting Activity: DEPT OF THE ARMY, 0413 AQ HQ

Service Type: Family Housing Maintenance
Mandatory for: US Navy, NAVFAC SOUTHWEST, Naval Base Ventura County, 311 Main Road, Point Mugu, CA
Designated Source of Supply: PRIDE Industries, Roseville, CA
Contracting Activity: DEPT OF THE NAVY, NAVFAC SOUTHWEST

Service Type: Custodial Services
Mandatory for: Veterans Affairs Nursing Home Care Unit, Pueblo, CO
Designated Source of Supply: Pueblo Diversified Industries, Inc., Pueblo, CO
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 259–NETWORK CONTRACT OFFICE 19

Service Type: Janitorial/Custodial
Mandatory for: Department of Veterans Affairs, Camp Hill Community Based Outpatient Clinic, 25 N 32nd Street, Camp Hill, PA
Designated Source of Supply: Goodwill Services, Inc., Harrisburg, PA
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 595–LEBANON

Michael R. Jurkowski,
Acting Director, Business Operations.

[FR Doc. 2023–04938 Filed 3–9–23; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the procurement list.

SUMMARY: The Committee is proposing to delete product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Comments must be received on or before:* April 9, 2023.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
7520–01–587–9632—Pen, Ballpoint, Retractable, 3 Pack, Blue, Medium Point
7520–01–587–9638—Pen, Ballpoint, Retractable, 3 Pack, Blue, Fine Point
7520–01–587–9645—Pen, Ballpoint, Retractable, Hybrid Ink, 6 Pack, Blue, Medium Point
7520–01–587–9646—Pen, Ballpoint, Retractable, Hybrid Ink, 6 Pack, Black, Medium Point
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
7105–00–139–7573—Coffee Table, 36″ x 36″ x 17″, English Oak, Laminated Top
7105–00–139–7601—Coffee Table, 48″ x 22″ x 17″, English Oak, Laminated Top
7105–01–462–1067—Coffee Table, 36″ x 36″ x 17″, English Oak, Natural Finish
7105–01–462–1068—Coffee Table, 48″ x 22″ x 17″, English Oak, Natural Finish
7105–00–139–7598—End Table, 26″ x 18″ x 21″, English Oak, Laminated Top
7105–01–462–1069—End Table, 26″ x 18″ x 21″, English Oak, Natural Finish
7105–00–139–7600—Lamp Table, 27″L x 27″W x 21″H, English Oak, Laminated Top
7105–01–462–1070—Lamp Table, 27″L x 27″W x 21″H, English Oak, Natural Finish
Designated Source of Supply: Knox County Association for Remarkable Citizens, Inc., Vincennes, IN
Contracting Activity: GSA/FAS FURNITURE SYSTEMS MGT DIV, PHILADELPHIA, PA

Service(s)

Service Type: Laundry Service
Mandatory for: Pennsylvania Air National Guard, 171st Air Refueling Wing, Aircrew Alert Facility, 300 Tanker Road, Coraopolis, PA
Designated Source of Supply: Hancock County Sheltered Workshop, Inc., Weirton, WV
Contracting Activity: DEPT OF THE ARMY, W7NX USPFO ACTIVITY PA ARNG
Service Type: Janitorial Service
Mandatory for: USDA Forest Service, White Mountain National Forest Headquarters, 71 White Mountain Dr, Campton, NH
Designated Source of Supply: Community Workshops, Inc., Boston, MA
Contracting Activity: FOREST SERVICE, ALLEGHENY NATIONAL FOREST

Michael R. Jurkowski,
Acting Director, Business Operations.

[FR Doc. 2023–04937 Filed 3–9–23; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, March 8, 2023; 10 a.m.

PLACE: The meeting will be held virtually and in person at Bethesda, MD.

STATUS: Commission Meeting—Closed to the Public.

MATTER TO BE CONSIDERED: *Briefing Matter.*

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary,

U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: March 7, 2023.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2023–05065 Filed 3–8–23; 11:15 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Withdrawal of Notice of Intent (NOI) To Prepare a Draft Environmental Impact Statement (DEIS) Pursuant to Section 203 of Water Resources Development Act of 1986 for the Wilmington Harbor Navigation Improvement Project Integrated Feasibility Study and Environmental Report, New Hanover and Brunswick Counties, NC

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent; withdrawal.

SUMMARY: The U.S. Army Corps of Engineers (USACE) is issuing this notice to advise Federal, State, and local governmental agencies and the public that USACE is withdrawing the notice of intent for the preparation of the DEIS pursuant to Section 203 of Water Resources Development Act (WRDA) of 1986 for the Wilmington Harbor Navigation Improvement Project Integrated Feasibility Study and Environmental Report, which was published in the **Federal Register** on September 12, 2019. Since publication of the NOI, the project was conditionally authorized under Section 403 of WRDA of 2020: Authorization of Projects Based on Feasibility Studies Prepared by Non-Federal Interests. USACE will be initiating a separate environmental review process for the Federal action related to the conditional authorization under Section 403 of WRDA of 2020.

DATES: The notice of intent to prepare an EIS published in the **Federal Register** on September 12, 2019 (84 FR 48131), is withdrawn as of March 10, 2023.

ADDRESSES: U.S. Army Corps of Engineers, Wilmington; 69 Darlington Avenue, Wilmington, North Carolina 28403.

FOR FURTHER INFORMATION CONTACT: Questions about the withdrawal of the Notice of Intent can be directed to Andrea Stolba, (910) 882–4936 at *andrea.m.stolba@usace.army.mil.*

SUPPLEMENTARY INFORMATION: A draft environmental report and integrated feasibility study for potential navigation improvements to the Wilmington Harbor Federal navigation channel leading from the Atlantic Ocean to the Port of Wilmington, North Carolina, was prepared in 2020 by the NCSPA under the authority granted by Section 203 of WRDA of 1986. The study area was the existing Wilmington Harbor federal navigation channel that originates offshore and extends approximately 38 miles through the Atlantic Ocean and up the Cape Fear River to the City of Wilmington, NC where it services the Port of Wilmington. The existing project provides for a channel −44 feet Mean Lower Low Water (MLLW) through the ocean bar and entrance channel, changing to −42 feet (MLLW) extending to just downstream of the Cape Fear Memorial Bridge. The Port of Wilmington has experienced increases in cargo volume and in the size of vessels calling at the port since the last major channel improvements were completed by the USACE under the Wilmington Harbor Project authorized under WRDA of 1996.

The Section 403 authorization for the navigation project, Wilmington Harbor, North Carolina, is conditioned upon the resolution of comments from the review assessment of the ASA(CW), titled ''Review Assessment of Wilmington Harbor, North Carolina Navigation Improvement Project Integrated Section 203 Study & Environmental Report (February 2020)'' and dated May 17, 2020.

Resolution of comments from the May 2020 ASA(CW) review assessment and any future Federal action related to the conditional authorization under Section 403 of WRDA of 2020 will comply with the requirements of NEPA (42 U.S.C. 4321 *et seq.*), Council on Environmental Quality's NEPA Implementing Regulations (40 CFR part 1500–1508), and USACE Procedures For Implementing NEPA (33 CFR part 230), and other related environmental review requirements. The USACE will initiate a separate environmental review process for the federal action pursuant to the Section 403 authorization.

Daniel H. Hibner,

Brigadier General, U.S. Army, Commanding.

[FR Doc. 2023–04904 Filed 3–9–23; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

Authorization of Subgrants for The Rhonda Weiss National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate IDEA Data in Accessible Formats

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: Pursuant to the Education Department General Administrative Regulations, the Department of Education (Department) authorizes the grantee receiving an award under the Rhonda Weiss National Technical Assistance Center to Improve State Capacity to Collect, Report, Analyze, and Use Accurate IDEA Data in Accessible Formats (Accessible Data Center), (Assistance Listing Number (ALN) 84.373Q), to make subgrants, subject to the limitations described in this notice.

DATES: Applicable Date: March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Rebecca Smith, U.S. Department of Education, 400 Maryland Avenue SW, Room 5076, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 987–0139. Email: *rebecca.smith@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The purpose of the Accessible Data Center is to improve State capacity to accurately collect, report, analyze, and use the Individuals with Disabilities Education Act (IDEA) Part B and Part C data reported under IDEA sections 616 and 618 in accessible formats for persons with disabilities, particularly those with blindness, visual impairments, motor impairments, and intellectual disabilities.

Subgrant Authorization: The Department's regulations in 34 CFR 75.708(a) prohibit a grantee from making a subgrant under this program unless authorized by statute or by a notice in the **Federal Register**. While subgranting is not authorized by statute for this program, and the Department's notice inviting applications (NIA) published in the **Federal Register** on July 12, 2022 (87 FR 41298) did not authorize subgranting for this program, the Department has determined that subgrants may be appropriate and necessary to enable the grantee to meet the purposes of the Accessible Data Center. Specifically, OSEP has

determined that allowing the grantee to form partnerships with eligible entities to implement grant requirements under this competition (including through the awarding of a subgrant) is necessary given the project's nature and need for a close, collaborative and substantive relationship between the grantee and the subgrant and the grantee's responsibility to oversee its subgrantee. Accordingly, through this notice, we authorize the grantee, Applied Engineering Management Corporation (AEM) to make subgrants on the terms outlined in this notice and consistent with AEM's application.

Under 34 CFR 75.708(b) and (c), if the grantee uses this subgranting authority, the grantee has the authority to award subgrants only to eligible entities identified in the grantee's approved application or selected through a competition under procedures established by the grantee, and the subgrants must be used only to directly carry out project activities described in the grantee's approved application and consistent with the purpose described in ALN 84.373Q and the priority and requirements established in the NIA. The Accessible Data Center grantee may make subgrants to the following eligible entities: State educational agencies; State lead agencies under Part C of the IDEA; local educational agencies (LEAs), including public charter schools that are considered LEAs under State law; institutions of higher education; other public agencies; nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

Further, under 34 CFR 75.708(d), the grantee must ensure that: (1) subgrants are awarded on the basis of the approved budget that is consistent with the grantee's approved application and all applicable Federal statutory, regulatory, and other requirements; (2) every subgrant includes all conditions required by Federal statutes and Executive Orders and their implementing regulations; and (3) subgrantees are aware of the requirements imposed upon them by Federal statutes and regulations, including the Federal anti-discrimination laws enforced by the Department, which are listed in 34 CFR 75.500. Additionally, as is true with any expenditures incurred under the Department's grant programs, Accessible Data Center expenditures must satisfy the OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, including the Federal cost principles in 2 CFR part 200, subpart E. Therefore, any subgrant and subgrantee expenditures must comply with the Federal cost principles, and the grantee, as a pass-through entity, must comply with the procedures for making subawards described in 2 CFR 200.332.

Note: This notice does not solicit applications.

Program Authority: 20 U.S.C. 1411(c), 1416(i), 1418(c), 1442; and the Consolidated Appropriations Act, 2021, Pub. L. 116–260, 134 Stat. 1182, 1601.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents published by the Department in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site. You may also access Department documents published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Katherine Neas,

Deputy Assistant Secretary. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2023–04909 Filed 3–9–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Request for Information—Foundation for Energy Security and Innovation (FESI); Correction

AGENCY: Office of Technology Transitions, Department of Energy.

ACTION: Request for information (RFI); correction.

SUMMARY: On February 15, 2023, the Department of Energy (DOE) published in the **Federal Register** a RFI seeking input on how DOE stakeholders may engage with the Foundation for Energy Security and Innovation (FESI). This document makes a correction to that notice.

FOR FURTHER INFORMATION CONTACT: Charlie Kong, Executive Assistant (contractor), U.S. Department of Energy, 1000 Independence Avenue SW, 20585; Phone: (202) 586–2000; email: *OTT@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Wednesday, February 15, 2023, in FR Doc. 2023–03199, on page 9877, please make the following correction:

Under the heading, **FOR FURTHER INFORMATION CONTACT**, first sentence, the contact information has been changed. The original contact was Mary Yamada, (240) 888–4568, *Mary.Yamada@hq.doe.gov.* The new contact is Mary Yamada, (202) 586–2000, *FESI.RFI@hq.doe.gov.*

Reason for Correction: Correcting the contact number and email address.

Signed in Washington, DC, on March 7, 2023

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–04951 Filed 3–9–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD23–1–000]

North American Electric Reliability Corporation; Order Approving Extreme Cold Weather Reliability Standards EOP–011–3 and EOP–012–1 and Directing Modification of Reliability Standard EOP–012–1

Before Commissioners: Willie L. Phillips, Acting Chairman; James P. Danly, Allison Clements, and Mark C. Christie.

1. On October 28, 2022, the North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO), submitted a petition seeking approval of proposed Reliability Standards EOP–011–3 (Emergency Operations) and EOP–012–1 (Extreme Cold Weather Preparedness

and Operations).[1] As discussed in this order, we approve proposed Reliability Standards EOP–011–3 and EOP–012–1, their associated violation risk factors and violation severity levels, and the newly defined terms Generator Cold Weather Critical Component, Extreme Cold Weather Temperature, and Generator Cold Weather Reliability Event.

2. It is essential to the reliable operation of the Bulk-Power System to ''ensure enough generating units will be available during the next cold weather event.'' [2] As the November 2021 Report found, the Bulk-Power System ''cannot operate reliably without adequate generation.'' When cold weather events such as Winter Storm Uri occur, with ''massive numbers of generating units'' failing, grid operators could have no other option than to shed firm customer load to prevent uncontrolled load shedding and cascading outages. And as unfortunately illustrated by Winter Storm Uri, ''[t]hese firm load shedding events . . . have very real human consequences. Millions went without heat . . . Hundreds died from hypothermia.'' [3] Accordingly, we approve proposed Reliability Standards EOP–011–3 and EOP–012–1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest.

3. While NERC's proposed Reliability Standards may ''provide new protections not currently found in any Reliability Standard,'' [4] EOP–012–1, in its current form, includes undefined terms, broad limitations, exceptions and exemptions, and prolonged compliance periods. Thus, we find that Reliability Standard EOP–012–1 requires improvement to address concerns, as discussed further below. Therefore, pursuant to section 215(d)(5) of the Federal Power Act (FPA),[5] we direct NERC to develop and submit modifications to Reliability Standard EOP–012–1 as discussed herein.

4. As an initial matter, we are concerned that use of the terms ''continuous run,'' ''commits or is obligated to serve'' and ''four hours or more,'' as well as the enumerated exemptions, obfuscates the extent of applicability of Reliability Standard EOP–012–1 to bulk electric system [6] facilities, and may not ensure that compliance is required for all ''generating units that are being depended upon to operate in cold weather and on which the reliability of the system depends.'' [7] We understand that the proposed applicability criteria is meant to avoid ''undue burden on those generating units that are not expected to operate in cold weather;'' [8] however, we find that excluded generating units should be the exception and not the rule.[9] Therefore, we direct NERC, pursuant to FPA section 215(d)(5), to modify Reliability Standard EOP–012–1 to ensure that it captures all bulk electric system generation resources needed for reliable operation and excludes only those generation resources not relied upon during freezing conditions.[10] As discussed further below, our directive to NERC is to clarify the language of the applicability section to align with NERC's explanation of the entities that should already be preparing to comply with the Standard, and should not need additional implementation time. Therefore, NERC should ensure the modified applicability section of Reliability Standard EOP–012 is implemented as of the effective date [11] of Reliability Standard EOP–012–1.

5. Further, as Reliability Standard EOP–011–2 requirements to implement and maintain cold weather preparedness plan(s) and associated training applies to all bulk electric system generating units, we defer our decision on whether to approve or modify NERC's proposed implementation date for Reliability Standard EOP–011–3 (and proposed retirement of Reliability Standard EOP–011–2) until NERC submits its revised applicability section for EOP–012. Allowing EOP–011–2 requirements to remain mandatory and enforceable until such time as the revised applicability is effective for EOP–012 will ensure all bulk electric system generating units are required to maintain cold weather preparedness plans.

6. In addition, we direct NERC to develop and submit modifications to Reliability Standard EOP–012–1 Requirements R1 and R7 to address concerns related to the ambiguity of generator-defined declarations of technical, commercial, or operational constraints that exempt a generator owner from implementing the appropriate freeze protection measures. We direct NERC to include in the Standard: objective criteria on permissible technical, commercial, and operational constraints, to identify the appropriate entity that would receive the generator owners' constraint declarations under EOP–012–1 Requirements R1 and R7, to describe how that entity would confirm that the generator owners comply with the objective criteria, and to describe the consequences of providing a constraint declaration. We direct NERC to modify this Standard to ensure that declarations cannot be used to opt out of mandatory compliance with the Standard or obligations set forth in a corrective action plan. We direct NERC to submit a revised Reliability Standard that addresses these concerns no later than 12 months after the date of issuance of this order.

7. Under Requirement R1 of EOP–012–1, generator owners must ''[i]mplement freeze protection measures that provide capability to operate for a period of not less than twelve (12) continuous hours at the Extreme Cold Weather Temperature'' or ''[e]xplain in a declaration any technical, commercial, or operational constraints . . . that preclude the ability to implement appropriate freeze protection measures to provide capability of operating at twelve (12) hours at the documented Extreme Cold Weather Temperature.'' [12] Yet, based on comments and our reading of the plain text of the Standard, we are concerned that the requirement as written is unclear whether new intermittent units

[1] The proposed Reliability Standards are not attached to this order. The proposed Reliability Standards are available on the Commission's eLibrary document retrieval system in Docket No. RD23–1–000 and on the NERC website, *www.nerc.com.*

[2] FERC, NERC, and Regional Entity Staff, *The February 2021 Cold Weather Outages in Texas and the South Central United States,* at 189 (Nov. 16, 2021), *https://www.ferc.gov/media/february-2021-cold-weather-outages-texas-and-south-central-united-states-ferc-nerc-and* (November 2021 Report).

[3] *Id.*

[4] NERC Petition at 7.

[5] 16 U.S.C. 824o(d)(5).

[6] NERC's Commission-approved bulk electric system definition defines the scope of the Reliability Standards and the entities subject to NERC compliance. *Revisions to Electric Reliability Organization Definition of Bulk Electric System and Rules of Procedure,* Order No. 773, 141 FERC ¶ 61,236 (2012), *order on reh'g,* Order No. 773–A, 143 FERC ¶ 61,053 (2013) *rev'd sub nom. People of the State of New York* v. *FERC,* 783 F.3d 946 (2d Cir. 2015); NERC Glossary at 5–7.

[7] NERC Petition at 30.

[8] *Id.*

[9] As discussed below, we also find that, even as to the limited set of excluded generating units, the obligation to have a cold weather emergency preparedness plan(s) and training should remain.

[10] 16 U.S.C. 824o(d)(5) (stating that the Commission, ''upon its own motion or upon complaint, may order the Electric Reliability Organization to submit to the Commission a proposed reliability standard or a modification to a reliability standard that addresses a specific matter if the Commission considers such a new or modified reliability standard appropriate to carry out this section'').

[11] This order uses the term ''effective date'' to mean the mandatory and enforceable date of the Standards, which, according to NERC's implementation plan, is 18 months after regulatory approval. NERC Petition at 50–51.

[12] Reliability Standard EOP–012–1, Requirement R1.

will be considered by all generator owners as being capable of operating for at least 12 continuous hours, and thus, must comply with the Requirement. Therefore, we direct NERC to modify the Standard to clarify Reliability Standard EOP–012–1 Requirement R1 to ensure that generators that are technically incapable of operating for 12 continuous hours (*e.g.,* solar facilities during winter months with less than 12 hours of sunlight) are not excluded from complying with the Standard. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

8. Under Requirement R2 of EOP–012–1, each generator owner is required to ''ensure its generating unit(s) add new or modify existing freeze protection measures as needed to provide the capability to operate for a period of not less than one (1) hour at the unit(s) Extreme Cold Weather Temperature.'' [13] We find that the one-hour continuous operations requirement in Reliability Standard EOP–012–1 Requirement R2 is too short of a period to adequately meet the purpose of the Standard to ensure generating units ''mitigate the reliability impacts of extreme cold weather.'' [14] Thus, we direct NERC to modify the one-hour continuous operations requirement of Reliability Standard EOP–012–1 Requirement R2. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

9. In addition, Reliability Standard EOP–012–1 does not require a deadline for, or a maximum duration of, corrective action plan implementation completion. We are concerned that the lack of a time limit for implementation completion of corrective action plans could allow identified issues to remain unresolved for a significant and indefinite period. Therefore, we direct NERC pursuant to FPA section 215(d)(5), to modify Reliability Standard EOP–012–1 Requirements R7 to include deadlines for implementation completion of corrective action plans, as recommended in the November 2021 Report.[15] We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

10. Additionally, we are concerned that generator owners will not have to implement freeze protection measures for existing generating units to provide them with the capability to operate for the specified durations at the Extreme Cold Weather Temperature under proposed EOP–012–1 Requirement R2 until 60 months from regulatory approval. Thus, we direct NERC to modify the EOP–012–1 60-month implementation plan for existing generating units. Although we are giving NERC the discretion to determine what the effective date should be shortened to, we also emphasize that industry has been aware of and alerted to the need to prepare their generating units for cold weather since at least 2011.[16] This finding was repeated in the 2019 South Central Event Report [17] and the November 2021 Report.[18] After the 2019 South Central Event Report, it was found that one third of the generator owners and operators surveyed ''still had no winterization provisions after multiple recommendations on winter preparedness for generating units.'' [19] NERC should consider the amount of time that industry has already had to implement freeze protection measures when determining the appropriate implementation period. Further, we find that a phased compliance within the implementation time for Reliability Standard EOP–012–1 Requirement R2 will also reduce reliability risks. To address these concerns, we direct NERC to modify the EOP–012–1 implementation plan for Requirement R2 to require a staggered implementation for existing unit(s) in a generator owner's fleet with an effective date of less than 60 months from regulatory approval.[20]

11. We also find it necessary that NERC ensure that Reliability Standard EOP–012–1 adequately addresses the reliability concerns related to generator owner constraint declarations, the adequacy of the Extreme Cold Weather Temperature definition, and determine whether future modification is needed, as discussed in more detail below. We note that, under the proposed implementation plan, it will be five years before certain requirements will be effective and a longer period before experiential data will be available. Notwithstanding our directives to shorten the implementation period for certain Requirements, waiting to collect data until after implementation will not provide timely information on the effectiveness of winterization efforts. However, section 1600 of NERC's Rules of Procedure provides a mechanism for data collections that could be used during the period prior to full implementation. Therefore, we direct NERC, pursuant to section 39.2(d) of the Commission's regulations,[21] to work with Commission staff to submit a plan no later than 12 months after the date of issuance of this order explaining how it will collect and assess data prior to and after the implementation of the following elements of Reliability Standard EOP–012–1: (1) generator owner declared constraints and explanations thereof; and (2) the adequacy of the Extreme Cold Weather Temperature definition.

I. Background

A. Section 215 and Mandatory Reliability Standards

12. Section 215 of the FPA provides that the Commission may certify an ERO, the purpose of which is to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.[22] Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.[23] Pursuant to section 215 of the FPA, the Commission established a process to

[13] Reliability Standard EOP–012–1, Requirement R2.

[14] NERC Petition at 29 (noting that freeze protection measures of the Standard would advance the reliability of the Bulk-Power System by helping to improve generator reliability in cold weather).

[15] *See, e.g.,* November 2021 Report at 187 (discussing Key Recommendation 1d, which, while recommending that the standards drafting team have flexibility to determine the specific timing for the corrective action plan to be developed and implemented after the outage, derate or failure to start, also recommends that the corrective action plan ''be developed as quickly as possible, and be completed by no later than the beginning of the next winter season.'').

[16] *See, e.g.,* FERC and NERC Staff, *Report on Outages and Curtailments During the Southwest Cold Weather Event of February 1–5, 2011: Causes and Recommendations,* at 208 (Aug. 2011), *https://www.ferc.gov/sites/default/files/2020-07/OutagesandCurtailmentsDuringtheSouthwestColdWeatherEventofFebruary1-5-2011.pdf* (recommending that each generator owner and operator should take steps to ensure that winterization is in place before the inter season and take preventative action in a timely manner).

[17] FERC and NERC Staff, *The South Central United States Cold Weather Bulk Electric System Event of January 17, 2018,* at 80–81 (July 2019), *https://www.ferc.gov/sites/default/files/legal/staff-reports/2019/07-18-19-ferc-nerc-report.pdf* (finding that the event was ''caused by failure to properly prepare or 'winterize' the generation facilities for cold temperatures'').

[18] November 2021 Report at 185 (finding that ''generation freezing issues were the number one cause of the Event, and the same frequently-seen frozen components reappear'').

[19] *Id.*

[20] *See e.g., Generator Verification Reliability Standards,* Order No. 796, 146 FERC ¶ 61,213, at PP 1–2 (2014) (approving Reliability Standard MOD–025–2 and its associated staggered implementation plan, which required 40% of applicable facilities to be verified in 2 years, 60% in 3 years, 80% in 4 years, and 100% in 5 years).

[21] 18 CFR 39.2(d) (2021) (the ERO shall provide the Commission such information as is necessary to implement section 215 of the FPA).

[22] 16 U.S.C. 824o(c).

[23] *Id.* § 824o(e).

select and certify an ERO,[24] and subsequently certified NERC.[25]

B. The February 2021 Cold Weather Reliability Event

13. On February 16, 2021, the Commission, NERC, and Regional Entity staff initiated a joint inquiry into the circumstances surrounding a February 2021 cold weather reliability event that affected Texas and the South-Central United States that culminated in a report identifying, among other things, recommendations for Reliability Standard improvements.[26] The November 2021 Report found that the February 2021 cold weather reliability event was the largest controlled firm load shed event in U.S. history; over 4.5 million people lost power and at least 210 people lost their lives during the event.[27] The November 2021 Report provided an assessment of the event as well as recommendations including, *inter alia,* Reliability Standard enhancements to improve extreme cold weather operations, preparedness, and coordination.[28]

14. After the February 2021 cold weather reliability event, but before the November 2021 Report was issued, NERC filed a petition for approval of cold weather Reliability Standards addressing recommendations from a 2018 cold weather event report.[29] In August 2021, the Commission approved NERC's modifications to Reliability Standards EOP–011–2 (Emergency Preparedness and Operations), IRO–010–4 (Reliability Coordinator Data Specification and Collection), and TOP–003–5 (Operational Reliability Data).[30] Reliability Standards IRO–010–4 and TOP–003–5 require that reliability coordinators, transmission operators, and balancing authorities develop, maintain, and share generator cold weather data.[31] EOP–011–2 requires generator owners to have generating unit cold weather preparedness plans and generator owners and generator operators to provide training for implementing the cold weather preparedness plans.[32]

C. NERC's Petition and Proposed Reliability Standards EOP–011–3 and EOP–012–1

15. On October 28, 2022, NERC filed a petition seeking approval on an expedited basis of Reliability Standards EOP–011–3 and EOP–012–1, the Standards' associated violation risk factors and violation severity levels, three newly-defined terms (Extreme Cold Weather Temperature, Generator Cold Weather Critical Component, and Generator Cold Weather Reliability Event), NERC's proposed implementation plan, and the retirement of currently approved EOP–011–2.[33] NERC explains that Reliability Standards EOP–011–3 and EOP–012–1 build upon the 2021-approved cold weather Reliability Standards by further strengthening the reliability of the Bulk-Power System during extreme cold weather conditions.[34] NERC maintains that proposed Reliability Standards EOP–011–3 and EOP–012–1 are consistent with key recommendations for standards' improvement from the November 2021 Report.[35] Specifically, NERC states that the proposed Reliability Standards contain new and revised requirements to advance the reliability of the Bulk-Power System through the implementation of freeze protection measures, enhanced weather preparedness plans, annual training, and the coordination of manual and automatic load shed.[36]

16. NERC states that the purpose of proposed Reliability Standard EOP–011–3 is to ensure that each transmission operator implements plans to mitigate operating emergencies and that such plans are coordinated within the reliability coordinator area. According to NERC, proposed Reliability Standard EOP–011–3 addresses Key Recommendation 1j from the November 2021 Report, which recommends that the circuits used for manual load shed be separated from the circuits used for automatic load shed or for critical loads.[37]

17. NERC proposes to modify approved Reliability Standard EOP–011–2 in multiple ways.[38] First, NERC proposes to remove Requirements R7 and R8 (generator cold weather preparedness plans and associated training) from EOP–011–2 and incorporate them into proposed Reliability Standard EOP–012–1 as Requirements R3 and R5, respectively.[39] Second, the added Requirements R1 and R2 of EOP–011–3 require that transmission operator emergency operating plans include provisions that minimize the overlap of manual load shed circuits, circuits that serve critical loads, and circuits that are used for underfrequency load shedding (UFLS) or undervoltage load shedding (UVLS).[40] Third, Requirement R1 requires the development of provisions that limit manual load shed of UFLS or UVLS circuits to situations warranted by system conditions.[41] Finally, Requirement R2 adds provisions for transmission operators to implement the operator-controlled manual load shed in accordance with Requirement R1. NERC also requests that the currently approved Reliability Standard EOP–011–2, which will go into effect on April 1, 2023, be retired immediately prior to the effective date of Reliability Standard EOP–011–3 and EOP–012–1, *i.e.,* 18 months after regulatory approval.[42]

18. NERC requests approval of a new Reliability Standard, EOP–012–1, which it states is meant to apply to generator owners and operators of generating units that are depended upon to operate during cold weather and Blackstart Resources. The purpose of Reliability Standard EOP–012–1 is to ensure that each generator owner develops and implements plans to alleviate the reliability effects of extreme cold weather on its generating units.[43] According to NERC, this new Reliability Standard addresses parts of Key Recommendation 1a as well as 1d, 1e, and 1f of the November 2021 Report.[44]

19. Proposed Reliability Standard EOP–012–1 has seven requirements, five of which are new (Requirements R1, R2, R4, R6, and R7) and two of which (Requirements R3 and R5) were moved and revised from approved Reliability Standard EOP–011–2. Reliability

[24] *Rules Concerning Certification of the Elec. Reliability Org.; & Procs. for the Establishment, Approval, & Enforcement of Elec. Reliability Standards,* Order No. 672, 114 FERC ¶ 61,104, *order on reh'g,* Order No. 672–A, 114 FERC ¶ 61,328 (2006).

[25] *N. Am. Elec. Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[26] *See* November 2021 Report at 9.

[27] *Id.*

[28] *Id.* at 184–212 (sub-recommendations 1a through 1j).

[29] 2019 South Central Event Report at 89.

[30] *See generally Order Approving Cold Weather Reliability Standards,* 176 FERC ¶ 61,119 (2021) (noting that the standards become enforceable on April 1, 2023).

[31] *Id.*

[32] *Id.*

[33] NERC Petition at 1–2.

[34] *Id.*

[35] *Id.* at 23; *see also* November 2021 Report at 184–92, 208–10 (Key Recommendations 1b, 1d, 1e, 1f, and 1j).

[36] NERC Petition at 23.

[37] *See id.* at 20 (citing the November 2021 Report at 208–10 (recommending that transmission operators use automatic load shed as a last resort)).

[38] Reliability Standard EOP–011–3, Requirements R3, R4, and R5 are unchanged from the approved version. *See Order Approving Cold Weather Reliability Standards,* 176 FERC ¶ 61,119 (approving EOP–011–2).

[39] *Id.;* NERC Petition at 45–46.

[40] NERC Petition at 46–49.

[41] *Id.* Ex. A–1, at 2–3.

[42] NERC Petition at 50.

[43] *Id.* at 29.

[44] *See id.* at 17–18 (citing the November 2021 Report at 184–89).

Standard EOP–012–1 Requirements R1 and R2 address a generator owner's obligation to implement freeze protection measures on its applicable units to provide them with the capability to operate at the Extreme Cold Weather Temperature for the unit's location.[45] Specifically, Requirement R1 requires either new units to be capable of operating at the Extreme Cold Weather Temperature for a continuous 12-hour period or that the generator owner declares that technical, commercial, or operational constraints prevent successful continuous operation. Requirement R2 requires either that existing units be capable of continuous operation for at least one hour at the Extreme Cold Weather Temperature or the generator owner to develop a corrective action plan to address the unit's inability to continuously operate successfully.[46]

20. Reliability Standard EOP–012–1 Requirements R3 and R5 require generator owners to implement cold weather preparedness plans (Requirement R3) and train their personnel on that plan annually (Requirement R5).[47] Requirement R3 also identifies the generator owner as the entity responsible for identifying the Extreme Cold Weather Temperature and Generator Cold Weather Critical Components for its unit(s); the generator owner must document both in its cold weather preparedness plan(s).

21. Reliability Standard EOP–012–1 Requirement R4 requires the generator owner to review its Extreme Cold Weather Temperature calculation, cold weather preparedness plan(s), and freeze protection measures every five years to determine if changes or updates are warranted.[48] Requirement R6 mandates that each generator owner experiencing an outage, failure to start, or derate due to freezing conditions develop a corrective action plan to address the identified causes. Lastly, Requirement R7 requires generator owners to implement corrective action plans developed pursuant to Requirements R2, R4, or R6, or explain in a declaration why they are not implementing corrective actions due to technical, commercial, or operational constraints.[49]

22. NERC requests the Commission approve the violation risk factors and violation severity levels for Reliability Standards EOP–011–3 and EOP–012–1. NERC states that the violation risk factors and violation severity levels for Reliability Standard EOP–011–3 did not change from approved Reliability Standard EOP–011–2. NERC also proposes violation risk factors and violation severity levels for new Reliability Standard EOP–012–1.[50]

23. NERC proposes an 18-month effective date for Reliability Standards EOP–011–3 and EOP–012–1, beginning on the first day of the first calendar quarter following regulatory approval.[51] All the requirements of Reliability Standard EOP–011–3 would be effective on this date.

24. Specific to the requirements of EOP–012–1, as of the effective date, generator owners will be required to update their cold weather preparedness plans to include the Extreme Cold Weather Temperature and Generator Cold Weather Critical Components, and document freeze protection measures for those components as required by EOP–012–1 Requirement R3 as well as provide unit-specific cold weather plan training on an annual basis as required by Requirement R5. Within 150 days of the effective date, generator owners will be required to develop corrective action plans, or declare constraints, as required by proposed EOP–012–1 Requirements R6 and R7. NERC also proposes that generator owners have an additional 42 months from the effective date of proposed Reliability Standard EOP–012–1 (*i.e.,* 60 months from the regulatory approval date) to come into compliance with the new freeze protection measures of EOP–012–1 Requirements R1 and R2 and an additional 60 months from the effective date (*i.e.,* 78 months from the regulatory approval date) to perform the first re-evaluation of the Extreme Cold Weather Temperature for their units and update cold weather preparedness plans and unit freeze protection measures, including developing any corrective action plans, as needed for proposed EOP–012–1 Requirement R4.

25. NERC explains that it considered these implementation timeframes necessary for generator owners to calculate the Extreme Cold Weather Temperature for each generating unit, to identify Generator Cold Weather Critical Components, and to perform the necessary engineering studies and analyses to identify and implement freeze protection measures that would provide for the required performance capability or to explain why such measures are precluded by technical, commercial, or operational constraints. NERC also states that generator owners need additional time to implement the freeze protection measures of EOP–012–1 Requirements R1 and R2 because of the significant engineering, design, analysis, and implementation efforts required to complete such work.[52]

26. NERC explains that it adopted a two-phase standard development project to develop, draft, and revise the extreme cold weather Reliability Standards in accordance with the November 2021 Report due to the extensive scope and demonstrated urgency of new and improved cold weather Reliability Standards.[53] NERC states that its October 28, 2022, petition represents phase one of its standard development project and that the remaining November 2021 Report recommendations will be addressed in the second phase of standards development. In phase two, NERC states that its standard drafting team also plans to consider industry concerns that arose in phase one.

27. Finally, NERC requests the Commission approve the proposed Standards in an expedited manner. NERC explains that, among other things, an expedited approval would provide regulatory certainty to entities seeking to implement the Standards ahead of the mandatory and enforceable dates.[54]

II. Notice of Filing and Responsive Pleadings

28. Notice of NERC's October 28, 2022, Petition was published in the **Federal Register**, 87 FR 67464 (Nov. 8, 2022), with comments, protests, and motions to intervene due on or before December 1, 2022.

29. On November 17, 2022, the Electric Power Supply Association (EPSA) filed a motion for an extension of time to submit comments. On

[45] *Id.* at 33–37.

[46] NERC defines the term ''corrective action plan'' as a ''list of actions and an associated timetable for implementation to remedy a specific problem.'' NERC, *Glossary of Terms Used in NERC Reliability Standards,* 11 (Dec. 2022) (NERC Glossary), *https://www.nerc.com/pa/Stand/GlossaryofTerms/Glossary_of_Terms.pdf. See also* Reliability Standard EOP–012–1, section 4.3.

[47] NERC Petition at 37–41 (stating that Requirements R3 and R5 were taken from Requirements R7 and R8 from Commission approved EOP–011–2 with modifications to ensure that a generator owner's cold weather preparedness plan includes the Extreme Cold Weather Temperature, Generator Cold Weather Critical Components, and freeze protection measures).

[48] *Id.* at 39–40 (this periodic review may require the generator owner to add or modify existing freeze protection measures to continue reliable operation).

[49] *Id.* at 43–45 (noting that the generator owner defines these constraints).

[50] *Id.* Ex. E at 7–20 (explaining NERC's justifications for each violation risk factor and violation severity level associated with Reliability Standard EOP–012–1).

[51] NERC Petition at 50–51.

[52] *Id.* at 52.

[53] *Id.* at 53 (noting that NERC anticipates completing development and filing with the Commission new or revised Reliability Standards by November 1, 2023).

[54] *Id.* at 55.

November 29, 2022, the Commission extended the comment period seven days to and including December 8, 2022.

30. The Commission received six sets of comments and five reply comments. The LS Power Development, LLC; Calpine Corporation; EPSA; PJM Power Providers Group (PJM Group); Transmission Access Policy Study Group (TAPS); the National Rural Electric Cooperative Association (NRECA); American Public Power Association (APPA); the Independent System Operators and Regional Transmission Organization Council (ISO/RTO Council); Edison Electric Institute (EEI); New England Power Generators Association, Inc. (NEPGA); and Invenergy LLC (Invenergy) filed timely motions to intervene. TAPS, the ISO/RTO Council, NEPGA, Invenergy, EPSA/PJM Group jointly, and the Texas Competitive Power Advocates (TCPA) filed timely comments. NERC filed reply comments out of time. Invenergy filed a motion for leave to reply and reply comments out of time. NEPGA/EPSA/PJM Group filed a joint out of time motion for leave to answer and joint answer to the ISO/RTO Council's comments. APPA/TAPS filed a joint out of time motion for leave to answer along with a joint answer to EPSA's comments. The ISO/RTO Council also filed an out of time motion for leave to answer along with an answer to the NERC's reply comments and NEPGA/EPSA/PJM Group's answer.

31. Commenters either did not address or were generally supportive of NERC's proposed modifications to Reliability Standard EOP–011–3.[55] Commenters raised concerns and requests for clarifications for NERC's proposed Reliability Standard EOP–012–1. The commenters range in their support for Reliability Standard EOP–012–1 from requesting that the Commission approve the Standard as filed with minor clarifications [56] to remanding the Standard to NERC with directives.[57] The comments on specific matters are summarized and addressed in the determinations below.

III. Determination

A. Procedural Matters

32. Pursuant to Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2021), the timely, unopposed motions to intervene serve to make the entities that filed them parties to this proceeding.

33. Rule 213(a)(2) of the Commission's Rules of Practice and Procedure, 18 CFR 385.213(a)(2) (2021), prohibits an answer to a protest or answer unless otherwise ordered by the decisional authority. Pursuant to Rule 214(d) of the Commission's Rules of Practice and Procedure, 18 CFR 385.214(d), we grant NERC and Invenergy's leave to file their late-filed reply comments given their interest in the proceeding and the absence of undue prejudice or delay. We also grant APPA/TAPS, NEPGA/EPSA/PJM Group, and the ISO/RTO Council's motions for leave to file out of time answers and we accept their answers because they have provided information that assisted us in our decision-making process.

B. Substantive Matters

34. Pursuant to section 215(d)(2) of the FPA, we approve Reliability Standards EOP–011–3 and EOP–012–1 as just, reasonable, not unduly discriminatory or preferential and in the public interest. As discussed in this order, we approve proposed Reliability Standards EOP–011–3 and EOP–012–1, their associated violation risk factors and violation severity levels, the newly defined terms Generator Cold Weather Critical Component, Extreme Cold Weather Temperature, and Generator Cold Weather Reliability Event. We defer our decision on whether to approve or modify NERC's proposed implementation date for Reliability Standard EOP–011–3 (and proposed retirement of Reliability Standard EOP–011–2) until NERC submits its revised applicability section for EOP–012, as discussed in more detail below. Absent the reforms adopted in Reliability Standards EOP–011–3 and EOP–012–1, the existing defects and inefficiencies exhibited during extreme cold weather conditions could be exacerbated and negatively affect reliability.

35. We find that Reliability Standard EOP–011–3 is an improvement over the 2021-approved cold weather Reliability Standards and enhances reliability by improving how transmission operators account for the overlap of manual load shed and automatic load shed in their emergency operating plans while also addressing the need to minimize the use of manual load shed that could further exacerbate emergencies and threaten system reliability. Commenters did not express concern with Reliability Standard EOP–011–3. Accordingly, we approve Reliability Standard EOP–011–3.

36. We find that Reliability Standard EOP–012–1 represents an improvement to the Reliability Standards and enhances the reliable operation of the Bulk-Power System by requiring generator owners to implement freeze protection measures, develop enhanced cold weather preparedness plans, implement annual trainings, draft and implement corrective action plans to address freezing issues, and provide certain cold weather operating parameters to reliability coordinators, transmission operators, and balancing authorities for use in their analyses and planning. We believe that these measures begin to address many of the issues identified as contributing to generating unit failures during extreme cold weather conditions, as noted in the November 2021 Report.[58] We also appreciate that NERC completed the modifications and development of Reliability Standards EOP–011–3 and EOP–012–1 in a timely manner.

37. Several commenters express concern regarding ambiguities in Requirements R1 and R7 of Reliability Standard EOP–012–1 pertaining to the generator owner declarations for ''technical, commercial, or operational constraints'' and ask the Commission to remand the Standard with direction to NERC for clarifications.[59] As discussed below, we agree that the provisions are ambiguous. However, we are not persuaded that there is sufficient cause to remand Reliability Standard EOP–012–1. Since we find that the Standard enhances the reliable operation of the Bulk-Power System, we conclude that the better course is to approve Reliability Standard EOP–012–1 so that it will take effect in a timely manner. Nevertheless, pursuant to our authority under FPA section 215(d)(5), we also direct NERC to develop modifications to address the concerns regarding Requirements R1 and R7, as well as other concerns we have identified as to other aspects of Reliability Standard EOP–012–1, without delaying the effective date of Reliability Standard EOP–012–1. This approach is consistent with Commission precedent.[60]

[55] *E.g.,* EPSA/PJM Group Comments at 3; NEPGA/EPSA/PJM Group Answer at 1; ISO/RTO Council Comments at 1–2, TAPS Comments at 1.

[56] *See* APPA/TAPS Answer at 2–9; ISO/RTO Comments at 1–3; ISO/RTO Answer at 1–2; TAPS Comments at 1.

[57] *See* EPSA/PJM Group Comments at 2–4; Invenergy Comments at 2, 13; NEPGA Comments at 2, 6–8; TCPA Comments at 2, 5–6.

[58] *See* November 2021 Report at 184–210.

[59] *See e.g.,* EPSA/PJM Group Comments at 7–9; ISO/RTO Council Comments at 10; NEPGA Comments at 7–8.

[60] *See e.g., Mandatory Reliability Standards for the Bulk-Power Sys.,* Order No. 693, 118 FERC ¶ 61,218, at P 10 (2007) (noting that ''[w]here a Reliability Standard requires significant improvement, but is otherwise enforceable, the Commission approves the Reliability Standard'' and ''directs the ERO to modify'' such Standards to address identified issues or concerns); *Version 5 Critical Infrastructure Prot. Reliability Standards,* Order No. 791, 145 FERC¶ 61,160, at PP 1–4 (2013),

Continued

38. While we understand that the implementation plan for Reliability Standard EOP–012–1 is designed to accommodate entities that may need time to determine Extreme Cold Weather Temperature values, identify cold weather critical components for applicable generating units, develop corrective action plans for freeze issues, perform various engineering analyses, provide the required training, and develop the necessary capabilities to satisfy revised data specifications, industry has been aware of and alerted to the need to prepare their generating units for cold weather since at least 2011. Therefore, we direct NERC to reduce the implementation time and to include a staggered implementation for Requirement R2 to reduce reliability risks. NERC should consider the amount of time that industry has already been alerted to the need to implement freeze protection measures when determining the appropriate implementation period. We also strongly encourage entities that are capable of complying with these Standards earlier than the mandatory and enforceable date to do so.

39. In addition to the directives to modify various aspects of Reliability Standard EOP–012–1, we also have concerns regarding generator owner constraint declarations and the adequacy of the Extreme Cold Weather Temperature definition that may be addressed with additional information. Therefore, pursuant to section 39.2(d) of the Commission's regulations,[61] NERC is hereby directed to work with Commission staff to submit a plan no later than 12 months after the date of issuance of this order on how it will collect and assess, through annual and event-based data submittals, the following elements of Reliability Standard EOP–012–1: (1) generator owner declared constraints and explanations thereof; and (2) the adequacy of the Extreme Cold Weather Temperature definition. NERC is hereby directed to submit periodic reports to the Commission providing the results of the assessments, as discussed in further detail below.

40. Below we address the following elements of Reliability Standard EOP–012–1: (1) jurisdiction; (2) the applicability of Reliability Standard EOP–012–1; (3) generator owner declarations for technical, commercial, or operational constraints; (4) the Extreme Cold Weather Temperature definition; (5) the absence of a deadline by which generator owners must implement new or modified freeze protection measures required by their corrective action plans; (6) cost recovery mechanisms; (7) other technical matters; and (8) annual and event-based data submittals.

1. Jurisdiction

a. Background

41. Section 215(a)(3) of the FPA defines ''Reliability Standard'' as:

> a requirement, approved by the Commission under this section, to provide for reliable operation of the bulk-power system. The term includes requirements for the operation of existing bulk-power system facilities, including cybersecurity protection, and the design of planned additions or modifications to such facilities to the extent necessary to provide for reliable operation of the bulk-power system, but the term does not include any requirement to enlarge such facilities or to construct new transmission capacity or generation capacity.[62]

42. The term ''Reliable Operation'' is defined by the statute as ''operating the elements of the bulk-power system within equipment and electric system thermal, voltage, and stability limits so that instability, uncontrolled separation, or cascading failures of such system will not occur as a result of a sudden disturbance . . . or unanticipated failure of system elements.'' [63]

b. Comments

43. EPSA/PJM Group and Invenergy assert that Requirements R1 and R2 of Reliability Standard EOP–012–1 would impose obligations on generator owners that ''fall outside of the scope'' of section 215 of the FPA.[64] Both provisions of Reliability Standard EOP–012–1 require generator owners to add new, or modify existing, freeze protection measures, with Requirement R1 pertaining to generating units with an operational date subsequent to the effective date of the Reliability Standard, and Requirement R2 pertaining to existing generating units.

44. EPSA/PJM Group argue that while the definition of Reliable Operation allows NERC to require modifications to address sudden disturbances and unanticipated failures, ''the language of the section is very clear that a Reliability Standard may only cover 'the operation' of existing facilities, where such operation shall only be 'within' equipment limits exclusively for the purpose of mitigating 'sudden disturbances' and 'unanticipated failures.' '' [65] In other words, according to EPSA/PJM Group, the statute authorizes the modification of existing facilities to reliably operate within their existing equipment limits but does not permit a Reliability Standard that changes a resource's equipment limits.[66] In the same vein, Invenergy asserts that it is unclear whether NERC has the authority under section 215 of the FPA to mandate retrofits on existing generators because the statutory definition of Reliability Standard is limited to requirements ''for the operation of existing bulk-power system facilities.'' [67] According to Invenergy, this language suggests that NERC can only mandate modifications when changes to a facility are already planned.[68]

45. In its reply comments, NERC asserts that the requirements of Reliability Standard EOP–012–1 that generator owners add freeze protection measures is within the scope of its authority and that commenters argue for an overly narrow interpretation of section 215 of the FPA.[69] According to NERC, EOP–012–1 satisfies a three-part framework for analyzing whether a proposed Reliability Standard is within the ERO's authority under the statute, namely that the Standard: (1) applies to users, owners or operators of the Bulk-Power System; (2) provides for the reliable operation of the Bulk-Power System; and (3) may include operational or design requirements, but may not address matters expressly excluded in the statute that were historically left to the jurisdiction of the states. Focusing on the third prong, NERC explains that Reliability Standard EOP–012–1 pertains to the operation of existing facilities and the design of planned additions or modifications to such facilities as needed to provide for the reliable operation of the Bulk-Power System, which is explicitly included in the statutory definition of Reliability Standard. NERC argues that, while the statutory definition of Reliability Standard specifically excludes ''any requirement to enlarge [existing] facilities or to construct new transmission capacity or generation capacity,'' EPSA/PJM Group's narrow reading of the definition would write into the statute a new exclusion that does not exist.

c. Commission Determination

46. We are not persuaded by EPSA/PJM Group and Invenergy's arguments and conclude that Reliability Standard

order on clarification and reh'g, Order No. 791–A, 146 FERC ¶ 61,188 (2014).

[61] 18 CFR 39.2(d).

[62] 16 U.S.C. 824o(a)(3).

[63] *Id.* § 824o(a)(4).

[64] *See* EPSA/PJM Group Comments at 5–7; Invenergy Comments at 13.

[65] *Id.* (footnotes omitted).

[66] *Id.* at 6.

[67] Invenergy Comments at 13.

[68] *Id.*

[69] NERC Reply Comments at 3–11.

EOP–012–1 Requirements R1 and R2 are within the statutory authority of the ERO and the Commission. We agree with NERC that EPSA/PJM Group and Invenergy narrowly interpret the terms ''Reliability Standard'' and ''Reliable Operation'' under section 215 of the FPA to reach an inaccurate conclusion regarding the ERO and the Commission's statutory authority.[70]

47. First, Requirements R1 and R2 of EOP–012–1 comport with the statutory definition of a Reliability Standard, which includes modifications to facilities to the extent that they are necessary to provide for the reliable operation of the Bulk-Power System.[71] Reliability Standard EOP–012–1 Requirement R1 requires generating units with a commercial operation date after the effective date of the Standard to implement freeze protection measures so that the unit is capable of continuous operation for at least 12 hours at the Extreme Cold Weather Temperature or for the generator owner to submit a declaration of a technical, commercial, or operational constraint that preclude its ability to comply with the Standard. Requirement R2 of EOP–012–1 requires existing generating units to either be capable of continuous operation for at least one hour at the Extreme Cold Weather Temperature or to develop a corrective action plan to resolve the issue. Thus, Requirements R1 and R2's freeze protection provisions serve an appropriate purpose, *i.e.,* to provide the ''Reliable Operation'' [72] of the Bulk-Power System as set forth in the definition of a ''Reliability Standard.'' [73] Further, neither of these requirements mandate the construction of new generation capacity or an expansion of the unit's generating capacity, which are the only relevant exclusions identified in the statutory definition of a ''Reliability Standard.'' [74]

48. Moreover, we reject EPSA/PJM Group's interpretation of the statutory definition of ''Reliable Operation'' as imposing a limitation or exclusion on an acceptable Reliability Standard. EPSA/PJM Group recognizes that under the definition of ''Reliable Operation'' NERC may require modifications to mitigate ''sudden disturbances'' and ''unanticipated failures'' of facilities to the extent necessary to provide for reliable Bulk-Power System operations.[75] Indeed, the Commission has previously approved Reliability Standards that require the implementation of physical modifications to improve reliability.[76] Rather, EPSA/PJM Group reads a limitation into the statutory definition of Reliable Operation—specifically ''within equipment . . . limits''—and argues that the proposed Reliability Standard would constitute an impermissible change to such equipment limits. However, we do not find this argument to be persuasive as the statutory language is not as narrow as EPSA/PJM Group suggests. When read in context, the definition of ''Reliable Operation'' contemplates that Reliability Standards should be designed so that facility equipment operates within specified limits to mitigate sudden disturbances and prevent unanticipated failures of system elements.[77]

49. EPSA/PJM Group seizes upon language from the ''Reliability Standard'' definition stating that the term ''includes requirements for the existing bulk-power system facilities. . . .'' [78] However, other than EPSA/PJM Group's assertion, there is no logical reason to tie together the language from these two definitions to limit the statutory scope for the requirements of a Reliability Standard. Rather, in context, the ''requirements for operation of existing . . . facilities'' passage continues ''. . . including . . . the design of planned additions or modification to such facilities to the extent necessary to provide for reliable operation of the bulk-power system.'' [79] This exactly describes the purpose of the freeze protection requirements in EOP–012–1, which are intended to reduce capacity that is forced off-line due to freezing conditions and to help ensure that such capacity is not forced off-line in newer units. Accordingly, we reject the arguments of EPSA/PJM Group that the requirements of EOP–012–1 are beyond our or NERC's authority.

50. For similar reasons, we reject Invenergy's argument that a requirement to ''retrofit'' existing generators exceeds the statutory definition of a Reliability Standard that is limited to requirements ''for the operation of existing bulk-power system facilities.'' [80] Again, Invenergy would read in an exclusion beyond the one explicit exclusion stated in the definition. Moreover, Invenergy's selected quote ignores the language that follows which includes requirements for ''the operation of existing bulk-power system facilities . . . and the design of planned additions or modifications to such facilities to the extent necessary to provide for reliable operation of the bulk-power system.'' [81] As discussed above, Requirements R1 and R2's freeze protection measures satisfy the latter provision, as the record shows that these modifications are necessary to provide for the reliable operation of the Bulk-Power System.

2. Applicability of Reliability Standard EOP–012–1

51. NERC's Rules of Procedure requires all Reliability Standards to include an applicability section that identifies (1) the registered functional entities required to comply with each Standard and (2) the bulk electric system facilities to which the requirements apply.[82] Reliability Standard EOP–012–1's applicability section applies to registered generator owners and generator operators. Further, the facilities subject to the requirements of the standard include bulk electric system generating units that are Blackstart Resources and any bulk electric system generating unit that:

> commits or is obligated to serve a Balancing Authority load pursuant to a tariff obligation, state requirement as defined by the relevant electric regulatory authority, or other contractual arrangement, rule, or regulation, for a continuous run of four hours or more at or below a temperature of 32 degrees Fahrenheit (zero degrees Celsius) [83]

52. NERC explains that the facilities section inclusions are ''carefully tailored to place the responsibility for cold weather preparedness on those generating units that are being depended on to operate in cold weather and on which the reliability of the system depends'' and that the facilities section exclusions are meant to avoid ''undue burden on those generating

[70] *Id.; see also* 16 U.S.C. 824o(a)(3)–(4).

[71] 16 U.S.C. 824o(a)(3).

[72] *Id.* section 824o(a)(4).

[73] *Id.* section 824o(a)(3).

[74] *Id.*

[75] EPSA/PJM Group Comments at 5 (citing to 16 U.S.C. 824(a)(4)).

[76] *See, e.g.,* Order No. 693, 118 FERC ¶ 61,218 at PP 1547, 1550 (approving Reliability Standard PRC–018–1, which requires the installation of disturbance monitoring equipment); *Mandatory Reliability Standards for Critical Infrastructure Protection,* Order No. 706, 122 FERC ¶ 61,040, at P 86 (2008) (providing entities with a reasonable amount of time to purchase and install new software and equipment for compliance); *PacifiCorp,* 141 FERC ¶ 61,140 P 1 (2014).

[77] 16 U.S.C. 824o(a)(4).

[78] EPSA/PJM Group Comments at 5.

[79] 16 U.S.C. 824o(a)(3).

[80] *See* Invenergy Comments at 13. *But see* NERC Petition Ex. A–2, at 3–8 (the term ''retrofit'' not appearing in proposed Reliability Standard EOP–012–1).

[81] 16 U.S.C. 824o(a)(3).

[82] *See* NERC, *Rules of Procedure,* App. 3A (Standard Process Manual), 5 (Mar. 2019), *N. Am. Elec. Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[83] Reliability Standard EOP–012–1, section 4.2.1.1.

units that are not expected to operate in cold weather.'' [84]

a. Comments

53. Invenergy questions which generator owner and generator operators must comply with Reliability Standard EOP–012–1. Specifically, Invenergy asserts that the applicability section of the Standard is not clear and unambiguous as to which entities must comply. Invenergy argues there are different types of generator owners that vary widely in how they, with their generating units, participate in electric markets, and requests that the Commission direct NERC to modify proposed Reliability Standard EOP–012–1 to provide specific criteria for which entities must comply.[85]

b. Commission Determination

54. We agree with Invenergy that the applicability of Reliability Standard EOP–012–1 is unclear and ambiguous. In its technical rationale and justification, NERC explains that Reliability Standard EOP–012–1 is not meant to require all generating units to provide capacity in extreme cold weather. Instead, the Standard applies to those generating resources that are ''obligated to serve Balancing Authority load during periods at or below freezing due to commitments pursuant to tariff obligations, state requirements defined by regulatory authorities, or other contractual arrangements, rules, or regulations are subject to the winterization requirements.'' [86] Further, NERC explains that the ''[t]he [standard drafting team] chose the four-hour timeframe in consideration of generators that typically do not commit during freezing conditions but are running when conditions drop below freezing for a short period of time . . . '' [87] Lastly, NERC states that the language is intended to act as a ''blanket inclusion of all [bulk electric system] resources that serve Balancing Authority load for a period of more than four hours in freezing conditions.'' [88]

55. Despite this additional description regarding the standard drafting team's intent, we are concerned that certain elements of the applicability criteria remain unclear and ambiguous. For example, in light of the multiple different approaches for participating in electricity markets, it may not be clear under what circumstances a generator owner is ''obligated to serve a Balancing Authority load.'' [89] Similarly, while the intent appears to be to exclude units that do not typically run during winter, it is unclear how the qualifier of ''for four hours or more'' is meant to be measured and applied in practice.

56. We find that NERC has not sufficiently supported the applicability criteria of EOP–012–1. Reliability Standard EOP–012–1 applies only to ''[a] Blackstart Resource'' or ''[a] Bulk Electric System generating unit that commits or is obligated to serve . . . pursuant to a tariff obligation, state requirement . . . , or other contractual arrangement, rule, or regulation, for a continuous run of four hours or more at or below a temperature of 32 degrees Fahrenheit (zero degrees Celsius). . . .'' [90] This applicability is further limited by enumerated exemptions set forth in section 4.2.2. NERC explains in its Petition that the Facilities section 4.2 of the Reliability Standard, that limits applicability to an unidentified subset of generating units, is meant to ''place the responsibility for cold weather preparedness on those generating units that are being depended on to operate in cold weather and on which the reliability of the system depends, while avoiding undue burden on those generating units that are not expected to operate in cold weather.'' [91] But based on commenter concerns and our reading of the plain text of the Reliability Standard, the extent of Reliability Standard EOP–012–1's applicability to bulk electric system facilities is unclear.

57. For example, it is unclear how the term ''continuous run'' would apply to intermittent resources, which by their nature are variable and, therefore, do not always run continuously. Ensuring clear applicability to intermittent generators is critical to ensuring that enough generating units are available during cold temperatures.

58. Moreover, to the extent it is NERC's intent to exclude units that do not typically run during winter from every requirement in the Standard, we have concerns that this is not clearly articulated in Reliability Standard EOP–012–1. In short, we are concerned that use of the terms ''continuous run,'' ''commits or is obligated to serve'' and ''four hours or more,'' as well as the enumerated exemptions, obfuscates the extent of applicability of Reliability Standard EOP–012–1 and may not ensure that compliance is required for all ''generating units that are being depended on to operate in cold weather and on which the reliability of the system depends.'' [92] Therefore, we direct NERC, pursuant to FPA section 215(d)(5), to modify Reliability Standard EOP–012–1 to ensure that it captures all bulk electric system generation resources needed for reliable operation and excludes only those generation resources not relied upon during freezing conditions.[93] As the directive is to clarify the language of the applicability section to align with NERC's explanation of the entities that should comply, there should be no need for additional implementation time. Therefore, NERC should ensure the modified applicability is implemented as of the effective date of Reliability Standard EOP–012–1.

59. Given the lack of clarity in the proposed applicability criteria for EOP–012–1, we are concerned that the standard could apply to significantly fewer generators than the existing Reliability Standard EOP–011–2 Requirements R7 and R8. Thus, as Reliability Standard EOP–011–2 requirements to implement and maintain cold weather preparedness plan(s) and associated training applies to all bulk electric system generating units, we defer our decision on whether to approve or modify NERC's proposed implementation date for Reliability Standard EOP–011–3 (and proposed retirement of Reliability Standard EOP–011–2) until NERC submits its revised applicability section for EOP–012. Allowing these requirements to remain mandatory and enforceable will ensure all bulk electric system generating units are required to maintain cold weather preparedness plans until such time as the revised applicability criteria are effective for EOP–012.

60. Furthermore, we are concerned that the proposed applicability criteria for EOP–012–1 and retirement of EOP–011–2 Requirements R7 and R8 will eliminate valuable information on cold weather preparedness of generating units that typically do not operate during the winter. Under EOP–011–2, all bulk electric system generating units must identify in cold weather preparedness plan(s) ''[g]enerating unit(s) cold weather data'' including ''[g]enerating unit(s) operating limitations in cold weather'' and

[84] NERC Petition at 30.

[85] Invenergy Comments at 4.

[86] NERC Petition, Ex. C–2, Technical Rationale and Justification for EOP–012–1 at 1.

[87] *Id.*

[88] *Id.* at 2.

[89] *Id.* at 1.

[90] Reliability Standard, EOP–012–1, section 4.2.

[91] NERC Petition at 30.

[92] *Id.* at 30.

[93] 16 U.S.C. 824o(d)(5) (stating that the Commission, ''upon its own motion or upon complaint, may order the Electric Reliability Organization to submit to the Commission a proposed reliability standard or a modification to a reliability standard that addresses a specific matter if the Commission considers such a new or modified reliability standard appropriate to carry out this section'').

''[g]enerating unit(s) minimum . . . design temperature . . . historical operating temperature . . . or current cold weather performance temperature determined by an engineering analysis.'' This data is to be exchanged with the reliability coordinator, transmission operator, and balancing authority for planning and operations. The November 2021 Report stated that ''[t]he intent behind requiring [generator owners] to identify and share with the [balancing authorities] and [transmission operators] the expected limitations of their generating units 'during local forecasted cold weather,' is to prevent grid operators from being surprised when large numbers of generating units that had committed to run are unable to do so during cold weather events.'' [94] Once EOP–012–1 goes into effect, and EOP–011–2 Requirements R7 and R8 are retired, we are concerned that generating units that do not typically operate during the winter will no longer provide this information to reliability coordinators, transmission operators, and balancing authorities. The loss of this information concerns us as the proposed applicability of EOP–012–1 recognizes that units that do not typically run during the winter may be called upon during emergencies. We therefore direct NERC to modify EOP–012–1 to ensure that this information remains available.

3. The Allowance of Exceptions for Generator Owner-Defined Technical, Commercial, or Operational Constraints

a. NERC Petition

61. Requirement R1 of EOP–012–1 requires a generator owner to either implement freeze protection measures on its existing units that provide capability to operate for a period of not less than 12 continuous hours at the Extreme Cold Weather Temperature for the unit or ''[e]xplain in a declaration any technical, commercial, or operational constraints that preclude the ability'' to comply with the requirement.[95] Similarly, Requirement R7 mandates that a generator owner implement each corrective action plan developed pursuant to Requirements R2, R4, or R6 ''or explain in a declaration why corrective actions are not being implemented due to any technical, commercial, or operational constraint as defined by the Generator Owner.'' [96]

b. Comments

62. Several commenters assert that the Requirements R1 and R7 in Reliability Standard EOP–012–1 could benefit from increased clarity. EPSA/PJM Group, NEPGA, and the ISO/RTO Council assert that the generator owner declaration of constraints outlined in Requirement R1 and Requirement R7 are overly broad and that there is no explanation of what technical, commercial, or operational constraints would be permissible for generator owners to avoid both the implementation of freeze protection measures and a corrective action plan.[97] Specifically, EPSA/PJM Group contend that the broad discretion towards generator owners to identify constraints in Requirements R1 and R7 may lead to generator owners avoiding the implementation of freeze protection measures (to lower their costs), thereby negatively interfering with competition.[98] The ISO/RTO Council states that this generator owner discretion to determine what constraints are valid without oversight could make enforcement difficult.[99] Similarly, Invenergy argues that this discretion could lead to uneven implementation and enforcement.[100] TCPA also requests that the Commission clarify that a lack of cost recovery is a commercial constraint to implementing Requirement R1 and R7.[101] Finally, commenters point out that there is no indication in the Standard of which entity should receive the declaration of constraints from the generator owner, if any.[102]

63. NERC, in its reply comments, states that provisions criticized by commenters including the ''constraints'' provision represents a balancing of competing opinions raised in the standards development process. NERC opines that the petition provides a sound technical basis for approving the Standards as filed, and reiterates that during the second phase project, ''NERC may propose further changes to enhance the clarity or effectiveness of the EOP–012 standard.'' [103]

c. Commission Determination

64. We share commenters' concerns regarding the uncertainty created by the proposed technical, commercial, or operational constraint provisions in Requirements R1 and R7, and that without criteria to guide the generator owners, or guardrails on what constitutes a legitimate technical, commercial, or operational constraint, entities may either benefit financially by avoiding the purpose of the Standard altogether or have declarations without auditable elements.[104] Indeed, instead of implementing freeze protection measures, Requirement R1 allows an entity to explain in a declaration the constraints that preclude the ability to comply. Requirement R7 allows an entity to explain in a declaration any technical, commercial, or operational constraints as defined by the generator owner that prevent its implementation of corrective actions set forth in a corrective action plan pursuant to Requirements R2, R4 and R6. We are also concerned that a generator owner may make the determination without informing planning and operational entities (*i.e.,* the reliability coordinator or balancing authority) that are expecting the reliable operation of the generating unit to its Extreme Cold Weather Temperature.

65. The Commission has previously encountered similar concerns regarding the vagueness and enforceability of Reliability Standards language. For example, in Order No. 693 the Commission approved Reliability Standards while also expressing concern that the term ''sabotage'' was too ambiguous.[105] Similarly, in Order No. 791 (approving Version 5 of the CIP Standards), the Commission raised concerns with vague language that required entities to ''identify, assess, and correct'' deficiencies. The Commission determined that the ambiguities resulted in an ''unacceptable amount of uncertainty'' and directed NERC to remove the ambiguous language and develop modifications within one year.[106] In both Order No. 693 and Order No. 791, the Commission approved NERC's proposed Reliability Standards as an improvement to reliability, while directing NERC to submit modifications to the Standards addressing the Commission's concern regarding vagueness of particular language. We conclude that a similar approach is appropriate in the immediate proceeding, given the improvements offered by Reliability Standard EOP–

[94] November 2021 Report at 190–91.

[95] NERC Petition Ex A–2, at 4.

[96] *Id.* at 4–6.

[97] EPSA/PJM Group Comments at 7–9; ISO/RTO Council Comments at 10; NEPGA Comments at 7–8.

[98] EPSA/PJM Group Comments at 7–9.

[99] ISO/RTO Council Comments at 10–11.

[100] Invenergy Comments at 8.

[101] TCPA Comments at 2–3, 7–8.

[102] *E.g.,* ISO/RTO Council Comments at 10.

[103] NERC Reply Comments at 13.

[104] *See, e.g.,* ISO/RTO Comments at 10 (cautioning that the ''broad undefined 'commercial' exemption could lead to the exception swallowing the rule'').

[105] Order No. 693, 118 FERC ¶ 61,218 at PP 1, 461.

[106] *See* Order No. 791, 145 FERC ¶ 61,160 at PP 49–53, 67, 69.

012–1 in addressing Bulk-Power System reliability during extreme cold weather events.

66. Accordingly, we direct NERC, pursuant to section 215(d) of the FPA, to develop and submit modifications to Reliability Standard EOP–012–1 Requirements R1 and R7 to address concerns related to the ambiguity of generator-defined declarations of technical, commercial, or operational constraints that preclude a generator owner from implementing the appropriate freeze protection measures and to ensure that the constraint declarations may not be used to opt-out of compliance with the Standard or obligations set forth in a corrective action plan. Specifically, we direct NERC to include auditable criteria on permissible constraints and to identify the appropriate entity that would receive the generator owners' constraint declarations under EOP–012–1 Requirements R1 and R7. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

67. TCPA requests that the Commission clarify that a ''lack of cost recovery'' is a commercial constraint to implementing Requirement R1 and R7.[107] TCPA argues that the ability of transmission service providers and others to receive regulated rates of return creates an uneven playing field for independent generation.[108] We decline to grant TCPA's proposed clarification. Granting TCPA's requested clarification would be tantamount to a blanket waiver for all generators that do not currently recover their costs through cost-of-service rates.[109] We believe it would be inappropriate to allow entities participating in competitive wholesale electric markets to simply opt-out of reliability improvements offered by NERC's proposal because they lack a dedicated cost recovery mechanism.

68. Additionally, to provide the Commission with an ongoing assessment of the risk to the Bulk-Power System, we direct that NERC assess the implementation of the declarations through annual informational data submittals filed with the Commission, discussed in more detail in section 8.

4. The Calculation of the Extreme Cold Weather Temperature at Which a Generating Unit Must Be Capable of Performing

a. NERC Petition

69. NERC proposes to define the term Extreme Cold Weather Temperature as equal to the lowest 0.2 percentile of the hourly temperatures measured in December, January, and February from January 1, 2000, through the date the temperature is calculated.[110] According to NERC, a statistical approach using modern weather data would advance the reliability of the Bulk-Power System while also avoiding being overly burdensome for those responsible for compliance.[111]

b. Comments

70. Some commenters express concern with the Extreme Cold Weather Temperature definition.[112] The ISO/RTO Council argues that only examining historical data from the year 2000 forward risks unnecessarily limiting the range of possible cold weather scenarios that the Standard is intended to address, and proposes an alternate calculation method.[113] NEPGA/EPSA/PJM Group counters that the ISO/RTO Council's proposed revisions materially change Reliability Standard EOP–012–1, and should the Commission adopt the ISO/RTO proposal, then efforts to comply with EOP–012–1 ''as drafted'' could be potentially futile.[114] Invenergy asserts that the Extreme Cold Weather Temperature definition is arbitrary because NERC did not measure the definition against any objective standard to ensure reliable operation.[115] Invenergy adds that the Extreme Cold Weather Temperature should be calculated by NERC and its Regional Entities to prevent uneven implementation and enforcement.[116] Invenergy also argues that it is unreasonable that the proposed Extreme Cold Weather Temperature ''will be heavily influenced by the colder nighttime temperatures, when there is no solar generation.'' [117]

c. Commission Determination

71. As noted above, the Extreme Cold Weather Temperature is equal to the lowest 0.2 percentile of the hourly temperatures measured in December, January, and February from January 1, 2000, through the date the temperature is calculated.[118] This method of determining the Extreme Cold Weather Temperature is a statistical approach, using the cumulative distribution of historical temperatures to determine the 0.2 percentile historical temperature. NERC's petition explains it relied on the Modernization and Associated Restructuring from the National Weather Service, which has higher quality and more granular temperature data in more locations, being completed in the year 2000 to justify the elimination of all pre-2000 historical weather data from consideration.[119]

72. We find that NERC's Extreme Cold Weather Temperature definition represents a reasonable starting point for reducing the level of risk. The use of the Extreme Cold Weather Temperature to establish a specific level of required freeze protection for resources is also a significant improvement over the current cold weather Reliability Standards, which contain no minimum temperature operating requirements.[120] With respect to the 0.2 threshold, we believe that NERC reasonably balanced a number of competing factors in setting the Extreme Cold Weather Temperature.[121] Similarly, while we agree with the ISO/RTO Council that additional data sources may be available, we find that NERC's consideration of data availability and its determination to rely on meteorological data starting in the year 2000 is reasonable. Similarly, as the Extreme Cold Weather Temperature definition is meant to apply uniformly regardless of generation type, we do not find it unreasonable that solar generators would need to meet an Extreme Cold Weather Temperature based on 24-hour-temperature data.[122]

73. Although we agree that NERC could have adopted other, potentially more robust approaches to defining the Extreme Cold Weather Temperature, we believe that other factors such as application, inspection, and

[107] TCPA Comments at 2–3, 7–8 (recommending that commercial constraints be expanded to include economic issues).

[108] *Id.* at 2.

[109] This order discusses cost recovery mechanisms in more detail in section 5.

[110] *Id.* at 24.

[111] *Id.* at 25–27 (relying on the Modernization and Associated Restructuring from the National Weather Service, which has higher quality, more granular temperature data in more locations).

[112] NEPGA/EPSA/PJM Group Answer at 3–4; ISO/RTO Comments at 6.

[113] ISO/RTO Council Comments at 7–9.

[114] NEPGA/EPSA/PJM Group Answer at 3–8 (requesting that the Commission *not* adopt the ISO/RTO Council's alternative Extreme Cold Weather Temperature proposal).

[115] Invenergy Comments at 7–8.

[116] *Id.* at 8.

[117] *Id.* at 7–8.

[118] NERC Petition at 24.

[119] *Id.* at 25–27.

[120] *See Order Approving Cold Weather Reliability Standards,* 176 FERC ¶ 61,119, at P 1.

[121] NERC Petition at 130 (relying on this approach to ensure that the Extreme Cold Weather Temperature does not result in an overly conservative design or preclude the generator owner from using historical operating data to show compliance).

[122] *See* Invenergy Comments at 7–8.

maintenance of the freeze protection measures and the associated training of generator owners or generator operators that perform these actions (all of which are requirements in the proposed Standard) should reasonably improve reliable operation of the Bulk-Power System. Further, recognizing that extreme cold weather temperatures could drop below the Extreme Cold Weather Temperature during future events, the need for periodic Extreme Cold Weather Temperature review [123] and updates [124] based on the new cold weather temperatures will help mitigate freezing issues over time, which could lessen the risk of freeze-related outages not being subject to corrective action plans.

74. Accordingly, we are not persuaded by commenters that modification to NERC's Extreme Cold Weather Temperature definition is warranted at this time. Nevertheless, based on the concerns expressed above, we direct that NERC assess the implementation of the definition through event-based informational data submittals filed with the Commission, discussed in more detail in section 8. Based on the results of NERC's informational data submittals to the Commission, the Commission will determine whether future modification to the Extreme Cold Weather Temperature definition is warranted.

5. The Absence of a Deadline by Which Generator Owners Must Implement the New or Modified Freeze Protection Measures Required by Their Corrective Action Plans

a. NERC Petition

75. Requirement R7 of EOP–012–1 mandates that a generator owner implement each corrective action plan developed pursuant to Requirements R2, R4, or R6, or ''explain in a declaration why corrective actions are not being implemented due to any technical, commercial, or operational constraint as defined by the Generator Owner.'' [125] Requirement R7 also requires that the generator owner update each corrective action plan if the actions or timetables change, until the corrective action plan implementation is completed. But Reliability Standard EOP–012–1 does not include a deadline for the implementation completion of such plans.

b. Comments

76. Some commenters express concern with Requirement R7 and the implementation timeline for generator owner-developed corrective action plans.[126] Specifically, the ISO/RTO Council requests modification because Requirement R7 does not explain when the implementation of the developed corrective action plans should occur.[127] The ISO/RTO Council also argues that it is unclear to which entity or entities the generator owner is supposed to provide its corrective action plan.[128] TCPA asserts that it is unclear from EOP–012–1 when the corrective actions outlined in the developed corrective action plans should be completed.[129]

c. Commission Determination

77. The NERC Glossary defines a ''corrective action plan'' as used in EOP–012–1 as a ''list of actions and an associated timetable for implementation to remedy a specific problem.'' [130] As such, the ''corrective action plan[s]'' in EOP–012–1 are required to contain a timetable for implementation completion and entities are required to implement actions consistent with the timelines defined in the corrective action plan under Requirement R7. While entities are required to adhere to the timelines as defined in their corrective action plans, some Reliability Standards establish a maximum time for completion while others do not. For example, the Commission directed NERC to add specific timelines for the completion of corrective action plans to mitigate geomagnetic disturbances in Reliability Standard TPL–007–1 (Transmission System Planned Performance for Geomagnetic Disturbance Events).[131] In contrast, the Commission has approved other Reliability Standards requiring a corrective action plan that do not require a specific deadline for the completion of the corrective action plan.[132]

78. In this instance, despite the lack of a deadline for completion, we find it appropriate to approve the Standard while also directing modification. We are persuaded that modifying the Standard to include a maximum time for implementation completion is reasonable for several reasons. First, having a requirement to implement a corrective action plan by a date certain will provide a significant level of risk reduction compared to the status quo. Second, the requirement to implement a corrective action plan and to identify any temporary operating limitations or effects to the cold weather preparedness plan that would apply to entities until the execution of the corrective actions by a date certain is an improvement to the Reliability Standards.[133] Finally, we do not find persuasive NERC's explanation that competition for expert resources and supply chain challenges may make setting a specific, uniform corrective action plan timeline for all generating units difficult. The November 2021 Report recommends that NERC's standard drafting team establish a maximum date that corrective action plans must be completed.[134] Otherwise, without a maximum time for implementation, we are concerned that the time it takes to complete the corrective action plans could allow identified issues to remain unresolved for a significant period.

79. Accordingly, we direct NERC pursuant to FPA section 215(d)(5) to modify Reliability Standard EOP–012–1 to address concerns related to the lack of an implementation timeframe for corrective action plans. Specifically, we direct NERC to include in the Standard a deadline or maximum period for the implementation completion of corrective action plans under the Standard. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

6. Cost Recovery Mechanisms

a. NERC Petition

80. Reliability Standard EOP–012–1 does not address cost recovery mechanisms. However, NERC's petition

[123] Reliability Standard EOP–012–1 already mandates a five-year Extreme Cold Weather Temperature re-calculation and updates to corrective actions where warranted.

[124] The proposed Standard requires updates regardless of the Extreme Cold Weather Temperature methodology used.

[125] NERC Petition at 43.

[126] *See, e.g.,* ISO/RTO Council Comments at 10–11; TCPA Comments at 4, 6.

[127] ISO/RTO Council Comments at 11.

[128] *Id.* at 10.

[129] TCPA Comments at 6.

[130] NERC Petition at 1013.

[131] *Reliability Standard for Transmission Sys. Planned Performance for Geomagnetic Disturbance Events,* Order No. 830, 156 FERC ¶ 61,215, at PP 101–04 (2016), *reh'g denied,* Order No. 830–A, 158 FERC ¶ 61,041 (2017) (directing NERC to modify TPL–007–1 to include a two-year deadline after the development of a CAP to complete the implementation of non-hardware mitigation and a four-year deadline to complete hardware mitigation).

[132] *See, e.g.,* PRC–004–6 (Protection System Misoperation Identification and Correction), Requirement R5 (requiring each transmission owner, generator owner, and distribution owner that owns a protection system component that caused misoperation to develop a corrective action plan or explain in declaration why corrective actions are beyond the entity's control).

[133] *Id.* Ex. A–2 at 6–7.

[134] November 2021 Report at 187 (Key Recommendation 1d).

recognizes that generator owners can recover costs through markets or cost recovery mechanisms approved by the state public utility commissions.[135]

b. Comments

81. Some commenters assert that Reliability Standard EOP–012–1 should address cost recovery.[136] TCPA asserts that the lack of a cost recovery for competitive generators is a commercial constraint to compliance with EOP–012–1 and requests that the Commission say so in its order.[137] The ISO/RTO Council asks the Commission to remove the commercial constraint option from EOP–012–1 altogether.[138] Invenergy argues that the November 2021 Report recognized that generators should be compensated for retrofits and that, while the NERC Reliability Standards process may not be the appropriate forum to address cost recovery, it is now incumbent on the Commission to address cost recovery for generators required to comply with EOP–012–1.[139] NEPGA contends that a market change or other cost recovery mechanism must be in place by the effective date of Reliability Standard EOP–012–1 and asks the Commission to recognize the FPA's cost recovery allowances.[140] EPSA/PJM Group ask that the Commission begin a proceeding under section 206 to address cost recovery for compliance with Reliability Standards.[141]

82. NERC and APPA/TAPS assert that cost recovery is outside the scope of what Reliability Standards can address.[142] Specifically, APPA/TAPS contend that the Commission should not act in this proceeding to provide competitive generators with a mechanism to recover cold weather Standard compliance costs because the FPA does not mandate special cost recovery mechanisms for competitive generators' section 215 compliance costs.[143] APPA/TAPS state that adopting a separate cost recovery mechanism for competitive generators' reliability compliance costs would be inconsistent with the Commission's market-based framework and could risk undercutting competitive markets.[144]

c. Commission Determination

83. We find that the question of whether existing market mechanisms provide an opportunity to recover the prudently incurred costs of compliance with the proposed Standard and the request to initiate a proceeding under FPA 206 are outside the scope of the instant proceeding.

7. Other Technical Matters

a. Comments

84. Commenters raise other technical concerns touching on a variety of elements of the Standard. For example, the ISO/RTO Council argues that NERC's implementation plan may ''discourage earlier compliance'' and that the Commission should enact a shorter implementation plan along with an exception process for generator owners that may ''legitimately need more time.'' [145] The ISO/RTO Council recommends revising the ''Generator Cold Weather Reliability Event'' definition to account for generating units rated at or below 200 MW.[146] The ISO/RTO Council also expresses concern that corrective action plans under the Standard only apply when the unit is unable to operate at or above the Extreme Cold Weather Temperature.[147] Additionally, the ISO/RTO Council questions how EOP–012–1 interacts with tariff requirements.[148]

85. EPSA/PJM Group requests that Requirements R1 and R2 be removed from EOP–012–1 and be replaced with a requirement that balancing authorities instead ensure weather-resilient generation.[149] For Reliability Standard EOP–012–1 Requirement R1, TAPS requests that compliance with the phrase ''provide the capability to operate'' be based on sound engineering judgment, meaning subsequent failures during cold weather not automatically lead to a violation since cold weather events cannot be simulated ahead of time.[150]

86. TCPA requests clarification of when the five-year clock in Requirement R4 begins and explanation how Requirement R7 requirement for corrective action plans could be effective 18 months after government approval when the standards for which the corrective action plans would address (*i.e.,* Requirements R2 and R4) are not effective until 60 and 78 months after government approval.[151] TCPA suggests that generator owners only be required to provide annual compliance progress reports.[152] TCPA also raises issue with EOP–012–1's violation severity level's lack of differentiation between single and multiple facilities.[153] Invenergy suggests revising NERC's ''Generator Cold Weather Reliability Event'' definition to align better with the bulk electric system definition to ensure that corrective action plans are only required when an actual Cold Weather Reliability Event occurs.[154] Invenergy and TCPA recommend eliminating the term ''continuous'' from EOP–012–1 Requirement R1 to reflect variable generation and that solar and wind plants are unable to operate continuously.[155]

87. NERC asserts that it is presently in phase two of its standard development process and that its standard drafting team is presently considering many of the issues raised in connection with this proceeding.[156] NERC encourages commenters in this proceeding to continue participating in NERC's standard development process so that their issues and concerns can be addressed.

b. Commission Determination

88. We share concerns with commenters regarding the implementation period of Reliability Standard EOP–012–1, although we acknowledge NERC's assertion that the time is necessary for generator owners to calculate the Extreme Cold Weather Temperature for each generating unit, to identify Generator Cold Weather Critical Components, and to perform the necessary engineering studies and analyses to identify and implement freeze protection measures that would provide for the required performance capability or to explain why such measures are precluded by technical, commercial, or operational constraints. To address these concerns, we direct NERC to revise EOP–012 to require a shorter implementation period and staggered implementation for unit(s) in a generator owner's fleet.[157] Such an approach will reduce reliability risks more quickly. Although we are giving

[135] NERC Petition at 44 (citing to November 2021 Report at 191–92).

[136] *See, e.g.,* EPSA/PJM Group Comments at 10–13.

[137] TCPA Comments at 2.

[138] ISO/RTO Council Comments at 10.

[139] Invenergy Comments at 11–13.

[140] NEPGA Comments at 2, 4–6.

[141] EPSA/PJM Group Comments at 11, 13 (proffering that the Commission could issue a show cause order pursuant to FPA section 206 to ensure that each ISO and RTO have cost recovery mechanisms in place).

[142] NERC Reply Comments at 10; APPA/TAPS Answer at 2–9.

[143] APPA/TAPS Answer at 2–8.

[144] *Id.* at 8–9.

[145] ISO/RTO Council Comments at 15–16.

[146] *Id.* at 16–17.

[147] *Id.* at 11–12.

[148] *Id.* at 13–15.

[149] EPSA/PJM Comments at 2.

[150] TAPS Comments at 5–6.

[151] TCPA Comments at 6.

[152] *Id.*

[153] *Id.* at 7.

[154] Invenergy Comments at 2, 5–6.

[155] *Id.* at 2, 9–10; TCPA Comments at 5.

[156] NERC Reply Comments at 13.

[157] *See, e.g.,* 146 FERC ¶ 61,213 at PP 1–2 (approving Reliability Standard MOD–025–2 and its associated staggered implementation plan).

NERC the discretion to determine what the effective date should be shortened to, we also emphasize that industry has been aware of and alerted to the need to prepare their generating units for cold weather since at least 2011. NERC should consider the amount of time that industry has already had to implement freeze protection measures when determining the appropriate shorter implementation period. We direct NERC to submit the revised implementation to Reliability Standard EOP–012–1 no later than 12 months after the date of issuance of this order.

89. For comments related to the ''continuous'' operation requirements of EOP–012–1, the Reliability Standard is clear that it requires generating units to be ''capable'' of operating continuously for 12 hours, and not that the units must actually operate when they would otherwise not be expected to operate. NERC states in its petition that the 12-hour requirement is a minimum.[158] However, we find the phrase ''continuous operation'' to be confusing and subject to conflicting interpretations. We also note that it creates confusion as to whether certain generating units can ever be capable of compliance. As Invenergy states, ''solar generators are not capable of operating in a 12-hour period that extends beyond daylight hours, and, typically when there are freezing temperatures, the sun does not even shine for 12 hours.'' [159] And while Invenergy states that the ''Standard Drafting Team indicated that the freeze protection measures must provide the level of protection that would allow for 12 continuous hours if the sun were to shine or the wind were to blow for the period,'' [160] the Reliability Standard Requirements in EOP–012–1 do not specify that.[161] Thus, we direct NERC to modify the Standard to clarify Reliability Standard EOP–012–1 Requirement R1 to ensure that generators that are technically incapable of operating for 12 continuous hours (*e.g.,* solar facilities during winter months with less than 12 hours of sunlight) are not excluded from complying with the Standard. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

90. We also find that the one-hour continuous operations requirement in Reliability Standard EOP–012–1 Requirement R2 is too short of a period to adequately meet the purpose of the Standard to ensure generating units ''mitigate the reliability impacts of extreme cold weather.'' [162] Thus, we direct NERC to modify the one-hour continuous operations requirement of Reliability Standard EOP–012–1 Requirement R2 to better align with the stated purpose of the Reliability Standard EOP–012–1. We direct NERC to submit the revised Reliability Standard no later than 12 months after the date of issuance of this order.

91. We find that it is premature to address TCPA's recommendation that generator owners only submit annual progress reports on compliance.[163] Nothing in proposed Reliability Standard EOP–012–1 mandates the submission of compliance reports and we are already directing NERC to address periodic data submittals in this order.

92. Finally, for suggested revisions to NERC's ''Generator Cold Weather Reliability Event'' definition to align better with the bulk electric system definition, and requests that Requirements R1 and R2 be removed from EOP–012–1 and be replaced with a requirement that balancing authorities instead ensure weather-resilient generation,[164] we decline to direct such modifications at this time.

8. Annual and Event-Based Data Submittals

93. NERC states that it plans to address data submittal requirements in phase two of its standard development process.[165] We find that such data submittals are essential to assess the performance of the Standards towards assuring the reliability of the Bulk-Power System. Specifically, we find that additional data and analysis is necessary to address the uncertainty created by the proposed technical, commercial, or operational constraint provisions, as discussed above in section 3. This data and analysis are essential to assess how the generating units' freeze protection measures (implemented to provide capability to operate at the Extreme Cold Weather Temperature) perform in future extreme cold weather events, as discussed above in section 4.

94. Accordingly, we direct that NERC, pursuant to section 39.2(d) of the Commission's regulations, work with Commission staff to develop and submit a plan within 12 months of the issuance of this order explaining how it will gather data and submit an analysis that will allow the Commission to understand the efficacy of, and monitor the ongoing risk posed by: (1) proposed technical, commercial, or operational constraint provisions in EOP–012–1, Requirements R1, R6, and R7; and (2) actual performance of freeze protection measures during future extreme cold weather events.

95. Regarding the proposed technical, commercial, or operational constraint provisions in EOP–012–1, Requirements R1, R6, and R7, NERC should work with Commission staff on the details of timing and what to include in its plan, which, at a minimum, should include collection of the following data: (1) the generating units that have declared constraints under EOP–012–1 and the megawatts of generation that they represent, organized by fuel type; (2) the megawatts of generation for which declarations have been made for each type of constraint (technical, commercial, or operational), organized by fuel type; (3) the rationale(s) for each declaration; (4) the megawatts of generation within the generation owner/operator's fleet currently capable of operating at each unit's Extreme Cold Weather Temperature; (5) the projected megawatts for which the generator owner/operator expects to complete corrective action plans for each year; (6) the projected megawatts for which the generator owner/operator expects to implement corrective action plans for each year; and (7) the megawatts of generating units identified as ''similar equipment'' [166] to which the generator owner has determined that the cause(s) for the Generator Cold Weather Reliability Event are also applicable, under R6.2, while also identifying any similar equipment that will receive a declaration. To provide the Commission with an ongoing assessment of the risk to the Bulk-Power System, NERC's plan should include an annual informational filing to the Commission beginning 12 months after the mandatory and enforceable date of the Standard. The informational filing should include data on the seven foregoing categories aggregated at an appropriate level (*e.g.,*

[158] Reliability Standard EOP–012–1 does not restrict longer duration commitments of generating units, whether based on tariff commitments, emergencies, or other conditions. *See* NERC Petition Ex. C–2 at 5 (explaining that the intent of Requirement R1 is to implement freeze protection measures such that facilities are capable of continuous operation *for not less than* 12 hours) (emphasis added).

[159] Invenergy Comments at 9.

[160] *Id.*

[161] Order No. 693, 118 FERC ¶ 61,218 at P 253 (''The most critical element of a Reliability Standard is the Requirements. As NERC explains, 'the Requirements within a standard define what an entity must do to be compliant . . . [and] binds an entity to certain obligations of performance under section 215 of the FPA.' '').

[162] NERC Petition at 29 (noting that freeze protection measures of the Standard would advance the reliability of the Bulk-Power System by helping to improve generator reliability in cold weather).

[163] TCPA Comments at 5.

[164] EPSA/PJM Comments at 2.

[165] NERC Petition at 54–55.

[166] For example, wind or solar equipment.

Regional Entity, balancing authority, etc.), and an analysis of the efficacy of the requirements of the Standard based on the data. Depending on the results of NERC's data collection and analysis, the Commission will determine whether further modifications are needed to the Standard.

96. NERC's plan should also include how it will analyze the performance of generating units' freeze protection measures (implemented to provide capability to operate at the Extreme Cold Weather Temperature) in future extreme cold weather events. Depending on the results of NERC's data collection and analysis, the Commission will determine whether further modifications are needed to the definitions or the Standard.

IV. Information Collection Statement

97. The information collection requirements contained in this Final Rule are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[167] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[168] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Comments on the collection of information are due within 60 days of the date this order is published in the **Federal Register**. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

98. The EOP Standards are currently located in the FERC–725S (OMB Control No. 1902–0270) collection. The collection is currently approved by OMB and contains Reliability Standards EOP–010–1, EOP–011–1, EOP–004–4, EOP 005–3, EOP–006–3, EOP–008–2 (Table 1). In Docket No. RD23–1–000, the Commission proposes to replace the current OMB approved Reliability Standard EOP–011–1 [169] with Reliability Standard EOP–011–3 (Table 2) and add a new information collection line item for Reliability Standard EOP–012–1 (Table 3).

99. The number of respondents below is based on an estimate of the NERC compliance registry for balancing authorities, transmission operators, generator operators, generator owners, and reliability coordinators. Reliability Standards EOP–011–3 and EOP–012–1 apply to balancing authorities, transmission operators, generator operators, and reliability coordinators. The Commission based its paperwork burden estimates on the NERC compliance registry as of November 4, 2022. According to the registry, there are 98 balancing authorities, 168 transmission operators, 981 generator operators, 1,107 generator owners, and 12 reliability coordinators. The estimates in the tables below are based on the change in burden from the current EOP Reliability Standards to the Reliability Standards approved in this order. The Commission based the burden estimates in the tables below on staff experience, knowledge, and expertise.

100. The estimates in the tables below are based, in combination, on one-time (years 1 and 2) and ongoing execution (year 3) obligations to follow the revised EOP Reliability Standards.

101. The Reliability Standard EOP–011–3 modifications transfer Requirements R7 and R8 to Reliability Standard EOP–012–1, as described below. For Reliability Standard EOP–011–3, transmission operators and to a much lesser extent, balancing authorities, still have a one-time cost to modify existing operating plans based on revisions to Reliability Standard EOP–011–3 (Requirements R1 and R2) and to mitigate operating emergencies related to cold weather conditions. Additionally, reliability coordinators will need to review the modified operating plans of the transmission operators. In year three and ongoing, the transmission operator and reliability coordinator estimates are lower to reflect lower paperwork burden for upkeep and review of the operating plans for emergencies based on the modified Reliability Standard EOP–011–3 to ensure that the new requirements are in place and that applicable entities are following those plans.

102. The new Reliability Standard EOP–012–1, which is applicable to 1,107 generator owners and 981 generator operators, contains several new requirements and two requirements from Reliability Standard EOP–011–2 that have been moved to Reliability Standard EOP–012–1. In year three and ongoing, the estimates are lower to reflect that the implementation plan(s) to mitigate the reliability effects of extreme cold weather conditions on generating units are in place and that entities are familiar with the EOP–012–1 requirements.

103. *Burden Estimates:* The Commission estimates the changes in the annual public reporting burden and cost as indicated in the tables below:

[167] 44 U.S.C. 3507(d).

[168] 5 CFR 1320 (2021).

[169] The currently OMB approved FERC–725S includes the burden related to Reliability Standard EOP–011–1. Reliability Standard EOP–011–1 was superseded by Reliability Standard EOP–011–2, which was approved by the Commission in Docket No. RD21–5–000 (issued August 24, 2021). Reliability Standard EOP–011–3, as noted in Docket No. RD23–1–000, will supersede Reliability Standard EOP–011–2; thus, the burdens resulting from Reliability Standard EOP–011–3 will be reflected in the FERC–725S information collection.

TABLE 1—CURRENT COSTS AND BURDEN RELATED TO FERC–725S (1902–0270)

Reliability standard and associated requirement	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response (4)	Total annual burden & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
EOP–010–1	181	1	181	20 hrs.; $1,660	3,620 hrs.; $300,460	$1,660
EOP–011–1	12	1	12	1,500 hrs.; $124,500	18,000 hrs.; $1,494,000	124,500
EOP–004–4, EOP–005–3, EOP–006–3, EOP–008–2.	280	1	280	250.58 [170] hrs.; $20,798	70,162.4 hrs.; $5,234,440	20,798
Total EOP	473				91,782 hrs.; $7,028,900	

TABLE 2—PROPOSED CHANGES DUE TO FINAL RULE IN DOCKET NO. RD23–1–000

Reliability standard & requirement	Type[171] and number of entity (1)	Number of annual responses per entity (2)	Total number of responses (1) * (2) = (3)	Average number of burden hours per response [172] (4)	Total burden hours (3) * (4) = (5)
FERC–725S—Proposed estimates due to RD23–1 for EOP–011–3					
One Time Estimate—Years 1 and 2 EOP–011–3					
EOP–011–3	168 (TOP)	1	168	60 hrs. $3,893.40	10,080 hrs. $654,091.2.
EOP–011–3 [173]	98 (BA)	1	98	6 hrs. $389.34	588 hrs. $38,155.32.
EOP–011–3 [174]	12 (RC)	1	12	28 hrs. $1,816.92	336 hrs. $21,803.04.
Sub-total of EOP–011–3 (One time)			278		11,004 hrs. $714,049.56.
Ongoing Estimate—Year 3 ongoing EOP–011–3					
EOP–011–3 [175]	168 (TOP)	1	168	10 hrs. $648.90	1,680 hrs. $109,015.20.
EOP–011–3 [176]	98 (BA)	1	98	10 hrs. $648.90	980 hrs. $63,592.20.
EOP–011–3 [177]	12 (RC)	1	12	14 hrs. $908.46	168 hrs. $10,901.52.
Sub-Total of EOP–011–3 (ongoing)			278		2,828 $183,508.92.
Sub-Total of ongoing burden averaged over three years.			92.67 (rounded)		942.67 hrs. (rounded) $61,169.64.
Proposed Total Burden Estimate of EOP–011–3.			370.67		11,946.67 hrs. $775,219.42 (rounded).

TABLE 3—PROPOSED CHANGES DUE TO FINAL RULE IN DOCKET NO. RD23–1–000 FOR EOP–012–1

Reliability standard & requirement	Type and number of entity (1)	Number of annual responses per entity (2)	Total number of responses (1) * (2) = (3)	Average number of burden hours per response [178] (4)	Total burden hours (3) * (4) = (5)
FERC—725S					
One Time Estimate—Years 1 and 2 EOP–012–1					
EOP–012–1 [179]	1,107 (GO)	1	1,107	150 hrs. $9,733.50	166,050 hrs. $10,774,984.50.
EOP–012–1	981 (GOP)	1	981	10 hrs. $648.90	9,810 hrs. $636,570.90.
Sub-Total for EOP–012–1 (one-time)			2,088	160 hrs. $10,382.40	175,860 hrs. $11,411,555.40.
Ongoing Estimate—Year 3 ongoing EOP–012–1					
EOP–012–1	1,107 (GO)	1	1,107	40 hrs. $2,595.60	40,680 hrs. $2,639,725.20.
EOP–012–1	981 (GOP)	1	981	10 hrs. $648.90	9,810 hrs. $636,570.90.
Sub-Total for EOP–012–1 (ongoing)			2,088	50 hrs. $3,244.50	50,490 hrs. $3,276,296.10.
Sub-Total of ongoing burden averaged over three years.			696		16,830 hrs. $1,092,098.70.
Proposed Total Burden Estimate of EOP–012–1.			2,784		192,690 hrs. $12,503,654.10.

TABLE 3—PROPOSED CHANGES DUE TO FINAL RULE IN DOCKET NO. RD23–1–000 FOR EOP–012–1—Continued

Reliability standard & requirement	Type and number of entity	Number of annual responses per entity	Total number of responses	Average number of burden hours per response [178]	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
Changes to FERC 725S by RD23–1–000					
FERC–725S modification	Current inventory (hours)	Current inventory (responses)	Total change due to RD23–1–000		
Removal of EOP–011–1	18,000	12	−18,000 hrs.; −12 responses.		
Updates to EOP–011–3			+11,946.67 hrs.; +370.67 responses.		
Addition of EOP–012–1			+192,690 hrs.; +2,784 responses.		

Titles: FERC–725S, Mandatory Reliability Standards for the Bulk-Power System; EOP Reliability Standards.

Action: Modifications to Existing Collections of Information in FERC–725S.

OMB Control Nos: 1902–0270 (FERC–725S).

Respondents: Business or other for profit, and not for profit institutions.

Frequency of Responses: On occasion (and proposed for deletion).

Necessity of the Information: Reliability Standards EOP–011–3 (Emergency Operations), and EOP–012–1 (Extreme Cold Weather Preparedness and Operations) are part of the implementation of the Congressional mandate of the Energy Policy Act of 2005 to develop mandatory and enforceable Reliability Standards to better ensure the reliability of the nation's Bulk-Power system. Specifically, the revised and new Reliability Standards ensure that generating resources are prepared for local cold weather events and that entities will effectively communicate the information needed for operating the Bulk-Power System.

Internal review: The Commission has reviewed NERC's proposal and determined that its action is necessary to implement section 215 of the FPA.

104. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

105. Comments concerning the information collections and requirements approved for retirement in this Final Rule and the associated burden estimates, should be sent to the Commission in this docket and may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: *oira_submission@omb.eop.gov.*

V. Document Availability

106. 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*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

107. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

108. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission orders:

(A) Reliability Standards EOP–011–3 and EOP–012–1, the associated violation risk factors and violation severity levels, and the newly defined terms Generator Cold Weather Critical Component, Extreme Cold Weather Temperature, and Generator Cold Weather Reliability Event, are hereby approved, as discussed in the body of this order.

(B) NERC is hereby directed to develop and submit, within 12 months of the date of issuance of this order, modifications to Reliability Standard EOP–012–1 as discussed in the body of this order.

(C) NERC is hereby directed to work with Commission staff to submit a plan no later than 12 months after the date of issuance of this order on how it will collect and assess data prior to and on the implementation of the following elements of Reliability Standard EOP–012–1: (1) generator owner declared constraints and explanations thereof; and (2) the adequacy of the Extreme

[170] Burden hours per response may also include any methods for improvement not limited to trainings, drills, simulations, testing, etc.

[171] TOP=Transmission Operator, BA=Balancing Authority, GO=Generator Owner, GOP=Generator Operator and RC=Reliability Coordinator.

[172] The estimated hourly cost (salary plus benefits) is a combination based on the Bureau of Labor Statistics (BLS), as of 2022, for 75% of the average of an Electrical Engineer (17–2071) − $77.02, mechanical engineers (17–2141) − $67.79. $77.02 + $67.79/2 = 72.405 × .75 = 54.303 ($54.30-rounded) ($54.30/hour) and 25% of an Information and Record Clerk (43–4199) $42.35 × .25% = 10.5875 ($10.59 rounded) ($10.59/hour), for a total ($54.30 + $10.59 = $64.89/hour).

[173] Reduce the estimate for balancing authorities from EOP–011–2 down from previous 60 hours to 6 hours for EOP–011–3.

[174] Reduce the estimate for reliability coordinators from EOP–011–2 down from previous 40 hours to 28 hours for EOP–011–3.

[175] Reduce the estimate for transmission operators from EOP–011–2 down from previous 50 hours to 10 hours for EOP–011–3.

[176] Reduce the estimate for balancing authorities from EOP–011–2 down from previous 50 hours to 10 hours for EOP–011–3.

[177] Reduce the estimate for reliability coordinators from EOP–011–2 down from previous 20 hours to 14 hours for EOP–011–3.

[178] The estimated hourly cost (salary plus benefits) is a combination based on the Bureau of Labor Statistics (BLS), as of 2022, for 75% of the average of an Electrical Engineer (17–2071) − $77.02, mechanical engineers (17–2141) − $67.79. $77.02 + $67.79/2 = 72.405 × .75 = 54.303 ($54.30-rounded) ($54.30/hour) and 25% percent of an Information and Record Clerk (43–4199) $42.35 × .25% = 10.5875 ($10.59 rounded) ($10.59/hour), for a total ($54.30 + $10.59 = $64.89/hour).

[179] The estimates for the generator owner and generator operator are being moved from the current EOP–011–2 to the new EOP–012–1.

Cold Weather Temperature definition, as discussed in the body of this order.

(D) NERC is hereby directed to assess annual and event-based data submittals to address the following elements of Reliability Standard EOP–012–1: (1) generator owner declared constraints and explanations thereof; and (2) the adequacy of the Extreme Cold Weather Temperature definition, and to submit periodic reports to the Commission providing the results of the assessments, as discussed in the body of this order.

By the Commission.

Issued: February 16, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–04875 Filed 3–8–23; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2513–091]

Green Mountain Power Corporation; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2513–091.

c. *Date Filed:* February 28, 2023.

d. *Applicant:* Green Mountain Power Corporation (GMP).

e. *Name of Project:* Essex No. 19 Hydroelectric Project.

f. *Location:* On the Winooski River in Chittenden County, Vermont. The project does not affect Federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Tedesco, Green Mountain Power Corporation, 163 Acorn Lane, Colchester, Vermont 05446; phone: (802) 655–8753 or email at *John.Tedesco@greenmountainpower.com.*

i. *FERC Contact:* Michael Tust at (202) 502–6522 or email at *michael.tust@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. *Project Description:* The existing project consists of: (1) a 494-foot-long concrete gravity dam consisting of a 61-foot-high non-overflow concrete abutment section and three overflow spillway sections 46-foot-high and each topped by a 5-foot-high inflatable rubber dam; (2) a 268-acre impoundment; (3) a 78-foot-wide, 36-foot-high concrete intake structure with two concrete wing walls, a steel trashrack with one-inch bar spacing, and an embedded downstream fishway; (4) two 3-foot-diameter steel penstocks and four 9-foot-diameter steel penstocks each running parallel to each other and extending underground from the dam to the powerhouse with lengths ranging from 382.9 to 389.3 feet; (5) a 154.6-foot-long, 93.5-foot-wide, and 55.7-foot-high, reinforced-concrete and brick powerhouse located 400 feet downstream of the intake housing four horizontal Francis-type turbines with an installed capacity of 2,223 kilowatts (kW) each and four horizontal shaft generators rated at 1,800 kilowatts each as well as a double horizontal Francis-type turbine (*i.e.,* minimum flow unit) with an installed capacity of 874 kW connected to a generator rated at 850 kW; (6) a 300-foot-long, 34.5-kilovolt overhead transmission line; and (7) appurtenant facilities. Green Mountain Power Corporation also owns and maintains the following recreation facilities: Overlook Park, an access site to the impoundment, an access site to the powerhouse tailrace area, and a canoe portage.

The downstream fish passage facility consists of two entrance gates each 3-feet-wide and 7.5-feet long located at the west end of the spillway. One entrance is located near the north end of the intake trashracks and the other is located closer to the center of the intake trashracks. The two entrances feed into a collection chamber behind the trashracks. The two collection chambers are connected via a 54-inch-diameter, 67-foot-long steel pipe which transports fish to an open channel sluice down the adjacent spillway and into a plunge pool. The plunge pool water level is controlled by a concrete weir with a bell-mouthed vertical slot with a 1-foot-wide opening which discharges flow into the bypassed reach.

GMP currently operates the project in a modified daily peaking mode while raising and lowering the impoundment level a maximum of 3 feet but now proposes to operate the project in run-of-river mode year-round while maintaining the impoundment at an elevation of 274.7 feet (under normal flow conditions). GMP would continue to provide minimum flows of 100 cubic feet per second (cfs) or inflow, if less, through the fish passage facility into the bypassed reach from April 15 through June 30 and from September 15 through December 15 and 50 cfs or inflow, if less, into the bypassed reach the remainder the year. The project has an average annual generation of 35,498 megawatt-hours.

l. *Location of the Application:* In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) 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 (P–2513). For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

m. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Procedural Schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Issue Deficiency Letter (if necessary)	March 2023.
Issue Additional Information Request (if necessary)	April 2023.
Notice of Acceptance/Notice of Ready for Environmental Analysis	August 2023.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	October 2023.

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: March 6, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–04996 Filed 3–9–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–34–000]

Southern Natural Gas Company, LLC; Notice of Request for Extension of Time

Take notice that on February 28, 2023, Southern Natural Gas Company, L.L.C (SNG) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until April 4, 2023, to complete its North System 2022 Project. SNG received a prior notice authorization for the North System 2022 Project on March 5, 2022 which authorized: (1) the construction of approximately 2.2 miles of 8-inch-diameter pipeline (Cordova Connector Line) in Walker County, Alabama; (2) the modification of existing facilities along the SNG system in Walker, Morgan, Calhoun, Jefferson, and Tuscaloosa counties, Alabama; and (3) the re-wheeling the existing Compressor Unit #1 at SNG's Providence Compressor Station in Tuscaloosa County, Alabama. The commission's prior notice regulations require SNG to complete the construction of the North System 2022 Project and make it available for service within one year from issuance, or by March 4, 2023.[1]

In SNG's request for an extension of time, SNG stated that as the construction of the Project was nearing completion, SNG determined that for operational safety a Remote Terminal Unit needed to be relocated to provide a 25-foot hazardous area radius with additional equipment at its Cordova Start site. Due to this scope addition and rainy condition SNG requests an extension of time in which to complete the Project from the one-year date of March 4, 2023, to the new projected completion date of April 4, 2023.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on SNG's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).[2]

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested,[3] the Commission will aim to issue an order acting on the request within 45 days.[4] The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.[5] The Commission will not consider arguments that re-litigate the issuance of the Certificate Order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.[6] At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.[7] The OEP Director, or his or her designee, will act on those extension requests that are uncontested.

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 COVID–19, issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original copy of the protest or intervention by U.S. mail to Kimberly D. Bose, Secretary Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Submissions by any other courier in docketed proceedings should be delivered to, Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on March 21, 2023.

Dated: March 6, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–04998 Filed 3–9–23; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 157.207(c).

[2] Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 39 (2020).

[3] Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2020).

[4] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

[5] *Id.* P 40.

[6] Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

[7] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–76–000]

ANR Pipeline Company; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on February 22, 2023, ANR Pipeline Company (ANR), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed in the above-referenced docket, a prior notice request pursuant to sections 157.205 and 157.216(b) of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act (NGA), and ANR's blanket certificate issued in Docket No. CP82–480–000,[1] for authorization to abandon one injection/withdrawal well and appurtenant facilities located at the Goodwell Storage Field in Newaygo County, Michigan, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

[1] *See Michigan Wisconsin Pipe Line Company,* 20 FERC ¶62,595 (1982).

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions concerning this application should be directed to David A. Alonzo, Manager, Project Authorizations, ANR Pipeline Company, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, at (832) 320–5477 or *david_alonzo@tcenergy.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

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 May 05, 2023. 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,[3] any person [4] 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,[5] and must be submitted by the protest deadline, which is May 05, 2023. 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 [6] and the regulations under the NGA [7] by the intervention deadline for the project, which is May 05, 2023. 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 May 05, 2023. 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 CP23–76–000 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 [8]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP23–76–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory

[2] 18 CFR (Code of Federal Regulations) § 157.9.

[3] 18 CFR 157.205.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 cfr 157.205(e).

[6] 18 CFR 385.214.

[7] 18 CFR 157.10.

[8] 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.

Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

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: David A. Alonzo, Manager, Project Authorizations, ANR Pipeline Company, 700 Louisiana Street, Suite 1300, Houston, TX 77002–2700 or *david_alonzo@tcenergy.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: March 6, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–04994 Filed 3–9–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0147; FRL–10772–01–OCSPP]

Metamitron; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received specific exemption requests from the Colorado and Nebraska Departments of Agriculture to use the pesticide metamitron (CAS No. 41394–05–2) to treat up to 35,000 acres of sugarbeets to control the weed, Palmer amaranth. The applicants propose the use of a new chemical which has not been registered by EPA. EPA is soliciting public comment before making the decision whether or not to grant the exemptions.

DATES: Comments must be received on or before March 27, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0147, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 506–2875; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. The Colorado and Nebraska Departments of Agriculture have requested the EPA Administrator to issue specific exemptions for the use of metamitron on sugarbeets to control Palmer amaranth.

Information in accordance with 40 CFR part 166 was submitted as part of the requests.

As part of this request, the applicants assert that emergency conditions exist due to insufficient means to control Palmer amaranth in sugarbeets, and the use of metamitron will help avert significant economic losses.

The Applicants propose to make no more than 2 applications of 32 fluid ounces of the unregistered product, Goltix 700 SC (containing 58.3% metamitron, equivalent to 5.84 lbs. of metamitron per gallon of product) on up to 14,700 acres of sugarbeets in Colorado, and 20,300 acres in Nebraska (total of 35,000 acres) from April 1 to May 31, 2023, using a potential maximum of 7,350 gallons of Goltix 700 SC in Colorado and 10,150 gal in Nebraska (total of 17,500 gallons of product, equivalent to 102,200 lbs. of metamitron).

This notice does not constitute a decision by EPA on the applications themselves. The regulations governing FIFRA section 18 at 40 CFR part 166.24(a)(1) require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (*i.e.,* an active ingredient) which has not been registered by EPA. The notice provides an opportunity for public comment on the applications.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemptions requested by the Colorado and Nebraska Departments of Agriculture.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 6, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2023–04871 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0074; FRL–10762–01–OCSPP]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by the registrants to voluntarily cancel their registrations of certain products and to amend certain product registrations to terminate one or more uses. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled or uses terminated only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before April 10, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0074, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html.*

II. What action is the Agency taking?

This notice announces receipt by EPA of requests from registrants to cancel certain pesticide product registrations and terminate certain uses of product registrations. The affected products and the registrants making the requests are identified in Tables 1–3 of this unit.

Unless a request is withdrawn by the registrant or if the Agency determines that there are substantive comments that warrant further review of this request, EPA intends to issue an order canceling and amending the affected registrations.

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
279–2862	279	Niagara Furadan 75 Base	Carbofuran (A) (090601/1563–66–2)—(75%).
279–3038	279	Furadan 85 DB	Carbofuran (A) (090601/1563–66–2)—(85%).

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Company No.	Product name	Active ingredients
279–3060	279	Carbofuran Technical	Carbofuran (A) (090601/1563–66–2)—(95%).
279–3114	279	Capture 2EC-Cal Insecticide/Miticide	Bifenthrin (A) (128825/82657–04–3)—(25.1%).
279–3244	279	Capture 1.15G Insecticide/Miticide	Bifenthrin (A) (128825/82657–04–3)—(1.15%).
279–3257	279	Double Threat CP Insecticide	Bifenthrin (A) (128825/82657–04–3)—(25.1%), Spinosad (A) (110003/131929–60–7)—(44.2%).
279–3271	279	Double Threat Insecticide	Bifenthrin (A) (128825/82657–04–3)—(12.2%), Spinosad (A) (110003/131929–60–7)—(10.7%).
279–3440	279	F9210–1 Insecticide	Bifenthrin (A) (128825/82657–04–3)—(7.87%), Imidacloprid (A) (129099/138261–41–3)—(13.83%), Zeta-Cypermethrin (A) (129064/)—(2.7%).
279–3613	279	F5555–2 MUP	Bifenthrin (A) (128825/82657–04–3)—(19%).
9779–293	9779	Phorate 20–G	Phorate (A) (057201/298–02–2)—(20%).
8660–153	8660	Parker Fertilizer + 0.2% Dimension	Dithiopyr (A) (128994/97886–45–8)—(.2%).
8660–154	8660	Herbicide Granules Formula D–17	Dithiopyr (A) (128994/97886–45–8)—(.17%).
8660–155	8660	Parker Fertilizer + 0.083% Dimension	Dithiopyr (A) (128994/97886–45–8)—(.083%).
8660–157	8660	Dimension 270–G A Granule Preemergence Turf Herbicide.	Dithiopyr (A) (128994/97886–45–8)—(.27%).
8660–158	8660	Polyon Turf Fertilizer Plus Dimension 75 Crabgrass Preventer.	Dithiopyr (A) (128994/97886–45–8)—(.075%).
8660–159	8660	Herbicide Granules Formula D–11	Dithiopyr (A) (128994/97886–45–8)—(.11%).
8660–160	8660	Polyon Turf Fertilizer Plus Dimension 140 Crabgrass Preventer.	Dithiopyr (A) (128994/97886–45–8)—(.14%).
8660–167	8660	Herbicide Granules Formula D6–25	Dithiopyr (A) (128994/97886–45–8)—(.25%).
32802–83	32802	Howard Johnson's Ronstar 1.0% Plus Turf Fertilizer Herbicide.	Oxadiazon (A) (109001/19666–30–9)—(1%).
43670–4	43670	Intersept PC–20	Phosphoric Acid, Bis(2-Ethylhexyl) Ester, Compd. With 2,2 & Apos;-(Coco Alkylimino) Bis (Ethanol) (129079/68649–38–7)—(13.28%), Phosphoric Acid, Mono(2-Ethylhexyl) Ester (111286/1070–03–7)—(3.54%), Phosphoric Acid, Mono(2-Ethylhexyl) Ester, Compds. With Diethanolamine N-Coco Alkyl Derivs. (1:1) (129080/120579–32–0)—(3.18%).
66222–1	66222	Captan 50–WP	Captan (081301/133–06–2)—(48.93%).
81598–12	81598	Rotam Dicamba Technical	Dicamba (029801/1918–00–9)—(98.9%).
CO–160002	100	Gramoxone SL 2.0	Paraquat dichloride—(30.1%).
ID–040011	62719	Stinger	Clopyralid, Monoethanolamine Salt (A) (117401/57754–85–5)—(40.9%).
ID–130001	61842	Linex 4L Herbicide	Linuron (A) (035506/330–55–2)—(40.6%).
ID–170008	62719	Stinger	Clopyralid, Monoethanolamine Salt (A) (117401/57754–85–5)—(40.9%).
FL–100004	279	Fyfanon ULV AG Ultra Low Volume Concentrate Insecticide.	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
FL–130002	279	Fyfanon 57% EC	Malathion (No Inert Use) (057701/121–75–5)—(57%).
FL–130003	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
GA–130002	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
IN–130001	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
IN–130002	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
KS–150005	13808	Zinc Phosphide Prairie Dog Bait	Zinc phosphide (Zn3P2) (088601/1314–84–7)—(2%).
MA–130001	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
MA–130002	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
MD–130003	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
MD–130004	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
MI–130002	69969	Avipel (Dry) Corn Seed Treatment	Anthraquinone (A) (122701/84–65–1)—(50%).
MI–140004	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
NC–130006	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Company No.	Product name	Active ingredients
NH–130001	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
NH–130002	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
NH–130003	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
NH–130004	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
NJ–130005	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
NJ–130006	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
NJ–130007	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
NJ–130008	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
NJ–130009	279	Fyfanon 57% EC	Malathion (NO INERT USE) (057701/121–75–5)—(57%).
OH–150002	279	Hero Insecticide	Bifenthrin (A) (128825/82657–04–3)—(11.25%), Zeta-Cypermethrin (A) (129064/)—(3.75%).
OR–020030	62719	Dithane DF Rainshield	Mancozeb (014504/8018–01–7)—(75%).
OR–170014	81880	Nexter SC Miticide/Insecticide	Pyridaben (A) (129105/96489–71–3)—(42.47%).
SD–090006	7969	Pristine Fungicide	Pyraclostrobin (A) (099100/175013–18–0)—(12.8%), Boscalid (A) (128008/188425–85–6)—(25.2%).
SD–150005	7969	Sharpen Powered by Kixor Herbicide	Saflufenacil (A) (118203/372137–35–4)—(29.74%).
TX–060018	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
TX–170006	279	Fyfanon ULV AG	Malathion (NO INERT USE) (057701/121–75–5)—(96.5%).
VA–130006	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
VA–130007	10163	Malathion 8	Malathion (NO INERT USE) (057701/121–75–5)—(79.5%).
WA–020028	62719	Dithane DF Rainshield	Mancozeb (A) (014504/8018–01–7)—(75%).
WA–090020	62719	Dithane F–45 Rainshield	Mancozeb (A) (014504/8018–01–7)—(37%).
WA–120009	100	Gramoxone SL 2.0	Paraquat dichloride—(30.1%).
WA–150011	71711	Moncut	Flutolanil (A) (128975/66332–96–5)—(70%).
WA–210007	91810	Romeo	Cerevisane (Cell Walls of Saccharomyces Cerevisiae Strain Las117) (100055/)—(94.1%).

TABLE 2—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR AMENDMENT

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
39967–107	39967	N–2000 Antimicrobial	Dodecylguanidine Hydrochloride (A) (044303/13590–97–1)—(35%).	Removal of sewage disposal lagoon and paint, coating and stain uses.
39967–115	39967	N–2001 Antimicrobial	Dodecylguanidine Hydrochloride (A) (044303/13590–97–1)—(35%).	Removal of sewage disposal lagoon use pattern.
39967–116	39967	Veriguard Plus	Dodecylguanidine Hydrochloride (A) (044303/13590–97–1)—(30%), O-Phenylphenol (No Inert Use) (A) (064103/90–43–7)—(10%).	Removal of textile, metalworking fluid, paints, coatings and stain and sapstain uses.
39967–124	39967	N–2050 Antimicrobial	Dodecylguanidine Hydrochloride (A) (044303/13590–97–1)—(35%).	Removal of sewage disposal lagoon use pattern.
39967–136	39967	Preventol DP 1021	Bronopol (A) (216400/52–51–7)—(21%), Dodecylguanidine Hydrochloride (A) (044303/13590–97–1)—(10.5%).	Removal of paints, coatings and stain use.

Table 3 of this unit includes the names and addresses of record for the registrants of the products listed in Table 1 and Table 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 and Table 2 of this unit.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR AMENDMENTS

EPA company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
7969	BASF Corporation, Agricultural Products, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528.
8660	United Industries Corp., D/B/A Sylorr Plant Corp., P.O. Box 142642, St. Louis, MO 63114–0642.
9779	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
10163	Gowan Company, LLC, 370 S Main St., Yuma, AZ 85366.
13808	SD Department of Agriculture & Natural Resources, Foss Bldg., 523 E Capitol Ave., Pierre, SD 57501–3182.
32802	Howard Johnson's Enterprises, Inc., 9675 S 60th Street, Franklin, WI 53132.
39967	Lanxess Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275–1112.
43670	Interface Research Corporation, Agent Name: Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603–5126.
61842	Tessenderlo Kerley, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
66222	Makhteshim Agan of North America, Inc., D/B/A Adama, 8601 Six Forks Road, Suite 300, Raleigh, NC 27615.
69969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.
71711	Nichino America, Inc., 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808.
81598	Albaugh, LLC, 1525 NE 36th Street, Ankeny, IA 50021.
81880	Canyon Group, LLC, C/O Gowan Company, 370 S Main Street, Yuma, AZ 85364.
91810	LeSaffre Yeast Corporation, Agent Name: Wagner Regulatory Associates, Inc., 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, DE 19707–0640.

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

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or
2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Requests

Registrants who choose to withdraw a request for product cancellation or use termination should submit the withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the action. If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to these requests for cancellation of product registrations and for amendments to terminate uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Tables 1 and 2 of Unit II.

For voluntary product cancellations, listed in Table 1 of Unit II, registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1 year after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the products identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Once EPA has approved product labels reflecting the requested amendments to terminate uses, registrants will be permitted to sell or distribute products under the previously approved labeling for a period of 18 months after the date of **Federal Register** publication of the cancellation order, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 3, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2023–04873 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–060]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)
Filed February 27, 2023 10 a.m. EST Through March 7, 2023 10 a.m. EST
Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20230039, Draft Supplement, USFS, ID, Hungry Ridge Restoration Project, Comment Period Ends: 04/24/2023, Contact: Jennie Fischer 208–983–4048.

Amended Notice

EIS No. 20230006, Draft, BLM, ID, Lava Ridge Wind Project, Comment Period Ends: 04/20/2023, Contact: Kasey Prestwich 208–732–7204.

Revision to FR Notice Published 01/20/2023; Extending the Comment Period from 03/21/2023 to 04/20/2023.

Dated: March 7, 2023.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2023–04927 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2023–0105; FRL–10559–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal Collection and Request for Comment; Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): ''Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h),'' identified by EPA ICR No. 2599.03 and OMB Control No. 2070–0213. This ICR represents a renewal of an existing ICR that is currently approved through January 31, 2024. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before May 9, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2023–0105 through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman (7602M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1204; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25 people) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h).

EPA ICR No.: 2599.03.

OMB Control No.: 2070–0213.

ICR status: This ICR is currently approved through January 31, 2024. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers the information collection activities associated with the prohibitions and restrictions on the following five persistent, bioaccumulative, and toxic (PBT) chemical substances: decabromodiphenyl ether (decaBDE) (Chemical Abstract Services Number (CASRN) 1163–19–5), phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937–41–7), 2,4,6-tris(tert-butyl)phenol (2,4,6–TTBP) (CASRN 732–26–3), pentachlorothiophenol (PCTP) (CASRN 133–49–3), and hexachlorobutadiene (HCBD) (CASRN 87–68–3). Specifically, the information collection activities associated with the downstream notification of the prohibitions in the rule for PIP (3:1) and the rule familiarization activities and recordkeeping requirement for all five PBT chemicals.

Burden statement: The average annual public reporting and recordkeeping burden for this collection of information is estimated to 0.74 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected are those that manufacture, process, distribute in commerce or use decabromodiphenyl ether (decaBDE), phenol, isopropylated phosphate (3:1) (PIP (3:1)), 2,4,6-tris(tert-butyl)phenol (2,4,6–TTBP), pentachlorothiophenol (PCTP), hexachlorobutadiene (HCBD), or

products or articles containing these chemicals.

Respondent's obligation to respond: Mandatory per TSCA section 6(h) and 40 CFR part 751.

Frequency of response: Occasional.

Total estimated number of potential respondents: 73.

Total estimated average number of responses for each respondent: 1.

Total estimated annual burden hours: 53 hours.

Total estimated annual costs: $4,299 (includes an estimated burden cost of $4,299 and an estimated cost of $0 for capital investment or maintenance and operational costs).

III. Are there changes in the estimates from the last approval?

There is decrease of 33 hours in the total estimated annual respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's updating of burden estimates and represents an adjustment. It results from the fact that some firms are no longer expected to incur recordkeeping and downstream notification costs since they are prohibited from using the chemical during the period this ICR covers.

In addition, EPA has updated this Supporting Statement to reflect the OMB request that EPA move towards using the 18-question format for ICR Supporting Statements that is used by other federal agencies and departments based on the submission instructions established by OMB in 1995. The 18-question format will replace the alternate format developed by EPA and OMB prior to 1995. The Agency does not expect the change in format to result in substantive changes to the presentation of the information collection activities or related estimated burden and costs. EPA welcomes comment on this new format in the context of this ICR.

IV. What is the next step in the process for this ICR?

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 pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 *et seq.*

Dated: March 6, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2023–04872 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0222; FRL–10567–01–OCSPP]

Cancellation Order for Certain Pesticide Registrations and Amendments To Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of certain product registrations, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a November 22, 2022, **Federal Register** Notice of Receipt of requests from the registrants listed in Table 3 of Unit II., to voluntarily cancel and amend certain product registrations to terminate uses of these product registrations. In the November 22, 2022, notice, EPA indicated that it would issue an order implementing the cancellations and amendments to terminate uses, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations and amendments are effective March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0222, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellations and amendments to terminate uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
228–713	228	TVC—Consumer Concentrate	Glyphosate-Isopropylammonium (103601/38641–94–0)—(5.03%), Imazapyr, Isopropylamine Salt (128829/81510–83–0)—(.089%).
228–714	228	TVC Consumer RTU	Glyphosate-Isopropylammonium (103601/38641–94–0)—(1.02%), Imazapyr, Isopropylamine Salt (128829/81510–83–0)—(.018%).
264–1156	264	QRD 406	Chenopodium Ambrosioides Var. Ambrosioides (599995/89997–47–7)—(100%).
264–1157	264	QRD 400	Chenopodium Ambrosioides Var. Ambrosioides (599995/89997–47–7)—(25%).
264–1187	264	Oberon Speed	Abamectin (122804/71751–41–2)—(1.08%), Spiromesifen (024875/283594–90–1)—(21.57%).
352–590	352	Dupont Cover Herbicide	Sulfentrazone (129081/122836–35–5)—(75%).
499–488	499	TC 223	Diflubenzuron (108201/35367–38–5)—(.25%).
499–501	499	Prescription Treatment Brand PT 224B	Propoxur (047802/114–26–1)—(1%).
524–543	524	Mon 78481 Herbicide	Carfentrazone-Ethyl (128712/128639–02–1)—(.19%), Glycine, N-(Phosphonomethyl)-Potassium Salt (103613/70901–12–1)—(44.76%).
707–304	707	Rocima 65 Industrial Microbicide	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N′-(1,1-Dimethylethyl)-6-(Methylthio)-(128996/28159–98–0)—(3.5%),3(2h)-Isothiazolone, 4,5-Dichloro-2-Octyl-(128101/64359–81–5)—(5%), Carbendazim (128872/10605–21–7)—(9%).
1381–198	1381	Execute S–P Insecticide	Pirimiphos-Methyl (108102/29232–93–7)—(57%), Spinosad (110003/131929–60–7)—(22.8%).
1381–221	1381	Imid+Meta+Tebu	Imidacloprid (129099/138261–41–3)—(12.7%), Metalaxyl (113501/57837–19–1)—(.82%), Tebuconazole (128997/107534–96–3)—(.62%).
1381–242	1381	IMT ST	Imidacloprid (129099/138261–41–3)—(11.374%), Metalaxyl (113501/57837–19–1)—(.607%), Tebuconazole (128997/107534–96–3)—(.455%).
8329–72	8329	Mosquito Larvicide GB–1111	Mineral Oil—Includes Paraffin Oil From 063503 (063502/8012–95–1)—(98.7%).
10163–230	10163	Mesurol Technical Insecticide	Methiocarb (100501/2032–65–7)—(98.8%).
10163–231	10163	Mesurol 75–W	Methiocarb (100501/2032–65–7)—(75%).
28293–123	28293	Unicorn Malathion Spray 1	Malathion (No Inert Use) (057701/121–75–5)—(57%).
34704–853	34704	Treflan 4L Herbicide	Trifluralin (036101/1582–09–8)—(43%).
34704–872	34704	Ginmaster Cotton Defoliant	Diuron (035505/330–54–1)—(6%), Thidiazuron (120301/51707–55–2)—(12%).
34704–895	34704	Colt	Clopyralid, Monoethanolamine Salt (117401/57754–85–5)—(11.3%), Fluroxypyr-Meptyl (128968/81406–37–3)—(12.3%).
34704–1004	34704	LPI Chlor-Metsul	Chlorsulfuron (118601/64902–72–3)—(62.5%), Metsulfuron (122010/74223–64–6)—(12.5%).
35935–94	35935	TVC-Super Concentrate	Glyphosate (417300/1071–83–6)—(43.68%), Imazapyr (128821/81334–34–1)—(.78%).
40810–11	40810	Irgarol 1051	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N′-(1,1-Dimethylethyl)-6-(Methylthio)-(128996/28159–98–0)—(98.6%).
40810–15	40810	Irgarol 1071	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N′-(1,1-Dimethylethyl)-6-(Methylthio)-(128996/28159–98–0)—(98.6%).
47000–107	47000	Prozap Malathion 57% Emulsifiable Liquid Insecticide-B.	Malathion (No Inert Use) (057701/121–75–5)—(57%).
66222–240	66222	Mana Diflubenzuron 80WG	Diflubenzuron (108201/35367–38–5)—(80%).
83822–1	83822	Weed2 & Feed Mulch	Dithiopyr (128994/97886–45–8)—(.0002%), Isoxaben (125851/82558–50–7)—(.0005%).
AR–100001	279	Spartan Charge Herbicide	Carfentrazone-ethyl 3.53%, Sulfentrazone 31.77%.
CA–170004	62719	Sequoia (Alternate), Closer SC (Active)	Sulfoxaflor 21.8%.
CA–170009	71693	Aspergillus Flavus AF36 Prevail	Aspergillus flavus strain AF36 .0008%.
FL–070003	62719	Cleanwave	Aminopyralid-Tripromine (005209/566191–89–7)—(1.92%), Fluroxypyr-Meptyl (128968/81406–37–3)—(20.22%).
KS–220002	264	USH0720®	Flufenacet (121903/142459–58–3)—(28.5%), Isoxaflutole (123000/141112–29–0)—(5.7%), Thiencarbazone-Methyl (015804/317815–83–1)—(2.28%).
MO–220001	264	USH0720®	Flufenacet (121903/142459–58–3)—(28.5%), Isoxaflutole (123000/141112–29–0)—(5.7%), Thiencarbazone-Methyl (015804/317815–83–1)—(2.28%).

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Company No.	Product name	Active ingredients
WA–210002	62719	Entrust SC	Spinosad 22.5%.
WI–130002	62719	Starane Ultra Herbicide	Fluroxypyr-meptyl 45.52%.
WI–150002	62719	Starane Ultra Herbicide	Fluroxypyr-meptyl 45.52%.

TABLE 2—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
1021–2720	1021	Pramix Technical Insecticide.	Permethrin (109701/52645–53–1)—(95%)	Wood Treatment & Protection Uses.
1021–2741	1021	Pramex Tech I	Permethrin (109701/52645–53–1)—(94%)	Wood Treatment & Protection Uses.
1021–2748	1021	Pramex B Technical Insecticide.	Permethrin (109701/52645–53–1)—(96.1%)	Wood Treatment & Protection Uses.
1021–2772	1021	Pramex TG	Permethrin (109701/52645–53–1)—(95.5%)	Wood Treatment & Protection Uses.
1021–2775	1021	Pramex 98.5% TG	Permethrin (109701/52645–53–1)—(98.5%)	Wood Treatment & Protection Uses.
5905–595	5905	Ethephon 3#	Citric Acid (I) (821801/77–92–9)—(%), Ethephon (A) (099801/16672–87–0)—(27%), Toluene (See Comments) (I) (880601/108–88–3)—(%), Water (I) (800001/7732–18–5)—(%), Xylene (I) (886802/1330–20–7)—(%).	Uses on residential turf/lawns, institutional turf, parks, recreational fields or sod farms.
5905–615	5905	Omni Brand Ethephon 2 lb.	Ethephon (A) (099801/16672–87–0)—(21.7%), Water (I) (800001/7732–18–5)—(70.6%).	Uses on residential turf/lawns, institutional turf, parks, recreational fields or sod farms.
35935–81	35935	NuFarm Ethephon MUP.	Ethephon (099801/16672–87–0)—(75%)	Non-Golf Turf Uses.
66222–151	66222	Ethephon 2SL	Ethephon (099801/16672–87–0)—(21.7%)	Turf Uses.
69969–7	69969	AV–5055	Anthraquinone (122701/84–65–1)—(18.6%)	Municipal Sites, Urban Areas, Sports Fields, Park Grounds, Home Lawns & Golf Courses.
69969–8	69969	Anthraquinone Technical.	Anthraquinone (122701/84–65–1)—(99.68%).	Municipal Sites, Urban Areas, Sports Fields, Park Grounds, Residential Buildings/Home Lawns & Golf Courses.
70506–459	70506	Ethephon 2#	Ethephon (099801/16672–87–0)—(21.7%)	Use on Institutional Turf.
70506–464	70506	Ethephon 3.9% H&G	Ethephon (099801/16672–87–0)—(3.9%)	Uses on Lawns and Parks.

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Tables 1 and 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed above.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS

EPA company No.	Company name and address
228	NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
264	Bayer CropScience, LP, Agent: Bayer CropScience, LLC, 801 Pennsylvania Avenue, Suite 900, Washington, DC 20004.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
352	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
499	BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709–3528.
524	Bayer CropScience, LP, 801 Pennsylvania Ave. NW, Suite 900, Washington, DC 20004.
707	Nutrition & Biosciences USA 2, LLC, 1652 Larkin Center Drive, 100 Larkin Center, Midland, MI 48642.
1021	McLaughlin Gormley King Company, D/B/A MGK, 7325 Aspen Lane N, Minneapolis, MN 55428.
1381	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
5905	Helena Agri-Enterprises, LLC, D/B/A Helena Chemical Comp, 225 Schilling Blvd., Suite 300, Collierville, TN 38017.
8329	Clarke Mosquito Control Products, Inc., 675 Sidwell Court, St. Charles, IL 60174.
10163	Gowan Company, LLC, 370 S Main St., Yuma, AZ 85366.
28293	Phaeton Corp., D/B/A Unicorn Laboratories, 1501 E Woodfield Road, Suite 200W, Schaumberg, IL 60173.
34704	Loveland Products, Inc., Agent: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
35935	NuFarm Limited, Agent: NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
40810	BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932.
47000	Chem-Tech, Ltd., 620 Lesher Place, Lansing, MI 48912.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
66222	Makhteshim Agan of North America, Inc., D/B/A Adama, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
69969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.
70506	UPL NA, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406.
71693	Arizona Cotton Research and Protection Council, Agent Name: IR–4 Project, Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS—Continued

EPA company No.	Company name and address
83822	Mulch Manufacturing, Inc., 6747 Taylor Road SW, Reynoldsburg, OH 43068.
89969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the November 22, 2022, **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations and amendments to terminate uses of products listed in Tables 1 and 2 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested cancellations and amendments to terminate uses of product registrations identified in Tables 1 and 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1 and 2 of Unit II, are canceled and amended to terminate the affected uses. The effective date of the cancellations that are subject of this notice is March 10, 2023. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II, in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI, will be a violation of FIFRA.

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

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of November 22, 2022 (87 FR 71321) (FRL–10372–01–OCSPP). The comment period closed on December 22, 2022.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States, and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

For voluntary cancellations, listed in Table 1 of Unit II, the registrants may continue to sell and distribute existing stocks of products listed in Table 1 of Unit II, until March 11, 2024, which is 1 year after publication of this cancellation order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Now that EPA has approved product labels reflecting the requested amendments to terminate uses, registrants are permitted to sell or distribute products listed in Table 2 of Unit II, under the previously approved labeling until September 10, 2023, a period of 18 months after publication of the cancellation order in this **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 3, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2023–04874 Filed 3–9–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 April 10, 2023.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions); 2200 N. Pearl St., Dallas, Texas 75201 or *Comments.applications@dal.frb.org*:

1. *A.N.B. Holding Company, Ltd., Terrell, Texas;* to acquire additional voting shares up to 37 percent of The ANB Corporation, and thereby indirectly acquire voting shares of The American National Bank of Texas, both of Terrell, Texas.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–

2034 or electronically to *Comments.applications@stls.frb.org*:

1. *Janwill Omni Holdings, LLC, Effingham, Illinois;* to become a bank holding company by acquiring additional voting shares up to 50 percent of Omni Bancorp, Inc., and thereby indirectly acquiring voting shares of Crossroads Bank, both of Effingham, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–04975 Filed 3–9–23; 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 March 27, 2023.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

Mary Elizabeth Thompson O'Connor, Sarasota, Florida; Kathleen Anne Thompson Brown, and Anne Therese Thompson Eckels, both of Kansas City, Missouri; Byron Gregory Thompson, Jr., Ann Arbor, Michigan; Mark Collins Thompson, Mission Hills, Kansas; Paul Joseph Thompson and Michael Scott Thompson, both of Leawood, Kansas; Timothy John Thompson, Phoenix, Maryland; Brian Christopher Thompson, Prairie Village, Kansas; as the Child Majority and the BGT Descendants' Committees, to become members of the Thompson Control Group, a group acting in concert to retain voting shares of CCB Financial Corporation and thereby indirectly retain voting shares of the Country Club Bank, both of Kansas City, Missouri.

Additionally, the following trusts to become members of the Thompson Control Group, to retain voting shares of CCB Financial Corporation and thereby indirectly retain voting shares of the Country Club Bank. *The B&J Thompson Trusts: fbo Mary Elizabeth Thompson O'Connor; fbo Kathleen Anne Thompson Brown; fbo Byron Gregory Thompson; fbo Mark Collins Thompson; fbo Paul Joseph Thompson; fbo Timothy John Thompson; fbo Brian Christopher Thompson; fbo Ann Therese Thompson Eckels; fbo Michael Scott Thompson, all U/I/T dated 12/31/92, as amended, and all of Kansas City, Missouri; the Country Club Bank, and the BGT Descendants' Committee, as co-trustees.*

Finally, the following trusts to become members of the Thompson Control Group, to acquire voting shares of CCB Financial Corporation and thereby indirectly acquire voting shares of the Country Club Bank. *The Brian Christopher Thompson Descendants' Trusts: fbo Brian Christopher Thompson, Jr.; fbo Jane O'Neil Thompson; fbo Madison Paige Thompson; fbo John Harrison Thompson; fbo Mason Henry Thompson, all u/a dated 2023, all of Kansas City Missouri; the Country Club Bank and the BGT Descendants' Committee, as co-trustees;* and

Brian Christopher Thompson, Leawood, Kansas; Jane O'Neil Thompson Austin, Texas; Madison Paige Thompson, John Harrison Thompson, and Mason Henry Thompson, all of Prairie Village, Kansas; Byron Gregory Thompson III, San Diego, California; Kelsey Anne Thompson Chun, East Grand Rapids, Michigan; Theresa Marie Thompson, Brooklyn, New York; Molly Jeanne Thompson Argersinger, Peter Joseph Thompson, Charles Paul Thompson, and Grace Elisabeth Thompson, all of Ann Arbor, Michigan; Amy Jeanne O'Connor Loup, Roeland Park, Kansas; Adelaide Thompson O'Toole, Fairway, Kansas; Mark Collins Thompson Jr., Overland Park, Kansas; William Wiedeman Thompson, New York, New York; Margaret Anne Thompson, August Gregory Thompson, Mary Jeanne Thompson, all of Mission Hills, Kansas; Timothy John Thompson, Jr., Norfolk, Virginia; Andrew Joseph Thompson, Silver Spring, Maryland; Tara Kathleen O'Connor Andris, Kensington, Maryland; Elizabeth Noel Thompson, Phoenix, Maryland; Catherine Hope Thompson, Chicago, Illinois; John Byron Eckels, Little Rock, Arkansas; Madeleine M. O'Connor Rau, John Joseph O'Connor IV, Thomas Pritchard Eckels, Jeanne Marie Eckels, William Thompson Eckels, and Molly Ann Eckels, all of Kansas City, Missouri; Michael Scott Thompson, Jr., Daniel James Thompson, Margaret Alyce Thompson, and Ryan Patrick Thompson, all of Leawood, Kansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–04976 Filed 3–9–23; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

[Notice–WWICC–2023–01; Docket No. 2023–0003; Sequence No. 1]

World War One Centennial Commission; Notification of Upcoming Public Advisory Meeting

AGENCY: World War One Centennial Commission.

ACTION: Meeting notice.

SUMMARY: Notice of this meeting is being provided according to the requirements of the Federal Advisory Committee Act. This notice provides the schedule and agenda for the May 19, 2023, meeting of the World War One Centennial Commission (the Commission). The meeting is available to the public. Dial in information will be provided upon request.

DATES: *Meeting date:* The meeting will be held on Friday, May 19, 2023, starting at 11:00 a.m. EST (10:00 a.m. CST), and ending no later than 12:00 p.m. EST (11:00 a.m. CST).

ADDRESSES: This meeting will be held in person and also available virtually. The meeting will convene in person at the National World War I Museum and Memorial located at 2 Memorial Drive, Kansas City, MO 64108. Virtual attendance is by reservation. Requests for dial in information may be made to *daniel.dayton@worldwar1centennial.org.*

Written Comments may be submitted to the Commission and will be made part of the permanent record of the

Commission. Comments must be received by 5:00 p.m. EDT, on May 12, 2023, and may be provided by email to *daniel.dayton@worldwar1centennial.org.*

Contact Mr. Daniel S. Dayton at *daniel.dayton@worldwar1centennial.org* to register to comment during the meeting's 30-minute public comment period. Registered speakers/organizations will be allowed five (5) minutes and will need to provide written copies of their presentations. Requests to comment, together with presentations for the meeting must be received by 5:00 p.m. EDT, on Friday May 12, 2023. Please contact Mr. Dayton at the email address above to obtain meeting materials.

FOR FURTHER INFORMATION CONTACT: Daniel S. Dayton, Designated Federal Officer, World War 1 Centennial Commission, 2043 Wilson Blvd., #17338, Arlington, VA 202–380–0725 (note: this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The World War One Centennial Commission was established by Public Law 112–272 (as amended), as a commission to ensure a suitable observance of the centennial of World War I, to provide for the designation of memorials to the service of members of the United States Armed Forces in World War I, and for other purposes.

Under this authority, the Committee will plan, develop, and execute programs, projects, and activities to commemorate the centennial of World War I, encourage private organizations and State and local governments to organize and participate in activities commemorating the centennial of World War I, facilitate and coordinate activities throughout the United States relating to the centennial of World War I, serve as a clearinghouse for the collection and dissemination of information about events and plans for the centennial of World War I, and develop recommendations for Congress and the President for commemorating the centennial of World War I. Further, the Commission oversees the design and construction of the national World War I Memorial in Washington, DC.

Agenda: Friday, May 19, 2023.

Old Business:

- Acceptance of minutes of last meeting.
- Public Comment Period.

New Business:

- Executive Director's Report—Executive Director Dayton.
- WWI Memorial Status Report.
- Preliminary Plan for Unveiling of central sculpture element—Ms. Meredith Carr.

Other Business:

- Chairman's Report.
- Set Next Meeting.
- Motion to Adjourn.

David Coscia,

Agency Liaison Officer, Office of Presidential & Congressional Agency Liaison Services, General Services Administration.

[FR Doc. 2023–04960 Filed 3–9–23; 8:45 am]

BILLING CODE 6820–95–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–23BI]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Research Data Center Proposal (RDC) Security Forms for Access to Confidential Data'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on December 12, 2022 to obtain comments from the public and affected agencies. CDC did not receive any comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Research Data Center Data Security Forms for Access to Confidential Data for the National Center for Health Statistics—Existing Collection In Use Without OMB Approval—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306(b)(4) of the Public Health Service (PHS) Act (42 U.S.C. 242k(b)(4)), as amended, authorizes the Secretary of Health and Human Services (DHHS), acting through the National Center for Health Statistics (NCHS), to receive requests for furnishing statistics to the public. NCHS receives requests for statistics from the public through the Standard Application Process (SAP). The public may apply to access confidential data assets held by a federal statistical agency or unit through the SAP for the purposes of generating statistics and developing evidence. Once an application for confidential data is approved through the SAP, NCHS will collect information to meet its data security requirements through its Data Security Forms. This information collection through the Data Security Forms will occur outside of the SAP.

As part of a comprehensive data dissemination program, the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), requires prospective researchers who need access to confidential data to

complete a research proposal and to self-select whether they need access to confidential data to answer their research questions. The RDC requires the researcher to complete a research proposal, so NCHS understands the research proposed. The completed proposal is sent to NCHS through the SAP portal for review and adjudication. If the research proposal is approved by NCHS, then the researcher must fill out two of three data security forms. If the researcher will access the data at a RDC, then the ''Data Access Form'' and the ''Designated Agent Form'' would need to be completed and returned to NCHS. If the researcher will access the data through the NCHS Virtual Data Enclave (VDE), then the ''VDE Data Use Agreement Form'' and the ''Designated Agent Form'' would need to be completed and returned to NCHS.

In order to capture the information needed to adjudicate a researcher's commitment to protect confidential NCHS data, researchers must complete and sign the data security forms. This request allows for both researcher signature and the time per response for a total estimated annual burden total of 110 hours. There is no cost to a researcher other than their time to complete the forms unless the researcher has to pay a nominal notary fee for services incurred. The resulting information will be used for NCHS internal purposes.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Researcher	Research Data Center proposal	110	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–04969 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23CV; Docket No. CDC–2023–0014]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Reducing Fatigue Among Taxi Drivers. The goal of this project is to evaluate two interventions, a training and a wrist-device that provide personalized daily fatigue scores, designed to enable taxi drivers to reduce their fatigue levels. This research study involves two parts: development of a fatigue management eLearning training tool designed for drivers-for-hire (*e.g.,* taxi drivers; ride sourcing drivers); and an evaluation of the effectiveness of this training alone and paired with the wrist-device that provides personalized daily fatigue scores.

DATES: CDC must receive written comments on or before May 9, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0014 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Reducing Fatigue Among Taxi Drivers—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Taxi drivers routinely work long hours and late night or early morning shifts. Shift work and long work hours are linked to many health and safety risks due to disturbances to sleep and circadian rhythms. Fatigue is a significant contributor to transportation-related injuries, most notably among shift workers. Such work schedules and inadequate sleep likely contribute to health issues and injuries among taxi drivers who experience a roadway fatality rate of 3.5 times higher than all civilian workers and had the highest rate of nonfatal work-related motor vehicle injuries treated in emergency departments. The urban and interurban transportation industry ranks the third highest in costs per employee for motor vehicle crashes. Tired drivers endanger others on the road (*e.g.,* other drivers, passengers, bicyclists, pedestrians) in addition to themselves and their passengers. An important approach to reducing fatigue-related risks is to inform employers and taxi drivers about the risks and strategies to reduce their risks.

The purpose of this project is to develop and evaluate a training program to inform taxi drivers and other drivers for hire who transport passengers of the risks linked to shift work and long work hours and evaluate strategies for taxi drivers to reduce these risks. Due to the pandemic, the study will be administered virtually. We are focused on taxi/rideshare drivers licensed in San Francisco, with approximately 45,000 drivers. The recruitment of 180 study participants and data collection procedures will be performed by NIOSH project personnel with support from a NIOSH contractor trained by the NIOSH project personnel. This research study involves two parts: development of a fatigue management eLearning training tool designed for drivers-for-hire (*e.g.,* taxi drivers; ride sourcing drivers); and an evaluation of the use of this tool as an intervention. The training tool will educate drivers about fatigue as a risk factor for motor vehicle crashes, the negative health and safety effects of fatigue, and how to reduce fatigue by improving sleep, health, nutrition and work schedules. There will be pre- and post-module knowledge tests to evaluate the training. The training will be offered online, free of charge, and will be viewable on multiple platforms (*e.g.,* smartphone, tablet, laptop). All participants will also wear a wristband actigraph used to measure sleep/wake cycles, which will serve as a second intervention. The actigraph data will provide a personalized daily measure of fatigue each participant can use as an external prompt to assess individual fatigue levels and trigger self-reflection on fitness to drive and act accordingly. A randomized pre-post with control group longitudinal study design will evaluate the training and the driver's response to feedback from the actigraph. Specifically, there are two intervention groups: (1) training plus actigraph fatigue level feedback and (2) training only with wearing actigraph but no fatigue level feedback. The control group will receive neither training nor feedback on fatigue levels from their actigraph. Participants will complete a baseline and follow-up Work and Health survey, sleep and activities diaries, and sleep health knowledge questions during each of five observation periods. The Work and Health survey administered in the first observation period will be more comprehensive and the abbreviated follow-up Work and Health surveys administered for the remaining observation periods will serve to capture only responses to questions that can change from one observation period to the next. Only participants randomly selected to take the training will complete a training evaluation survey used to strengthen the training's effectiveness. Data will also be collected from company installed in-vehicle monitoring systems on safety critical events (*e.g.,* hard braking, speeding) already collected on all drivers as a direct measurement of fatigue-related driving performance events used to validate self-report data. As part of their daily sleep and health diaries drivers will be asked to complete three-minute psychomotor vigilance tests (PVTs) five times throughout the day to directly measure alertness using an app installed on an electronic device. At the end of the data collection period the training will be offered to the remaining study participants who will be provided an opportunity, but no remuneration, to complete the training and training survey.

Study staff will use the findings from this evaluation to improve the training program, including content and delivery, as well as compare fatigue between intervention groups. Potential impacts of this project include improvements in work behaviors for coping with shift work and long work hours and an objective reduction in fatigue compared to the control groups. This project is poised to have considerable impact in the contribution of an evidence base for effective interventions that could be used by other taxi companies and drivers for ride sourcing companies to promote strategies in road safety.

The burden table lists 120 of the 180 taxi drivers in the study will complete the online training and evaluation (approximately three hours). All drivers (180) will complete the Work and Health survey, and the knowledge survey each week of the study (five times each per participant). Each participant will complete the sleep and activity diary five times a day, each day for 35 days (175 times total) which will require approximately two minutes for each response. There will also be three meetings for recruitment and enrollment (once), fitting the actigraph (weekly), and a final meeting (weekly). The total estimated annualized burden hours is 2,700. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Taxi Drivers	Online Training & Evaluation	120	1	180/60	360
	Sleep & Activities Diary	180	175	2/60	1,050
	Work & Health Survey	180	5	45/60	675
	Knowledge survey	180	5	15/60	225
	Recruitment & Informed Consent	180	1	30/60	90
	Initial Meeting (Fit Actigraph)	180	5	10/60	150
	10-minute meeting (turn in devices, turn in diary, receive remuneration).	180	5	10/60	150

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total					2,700

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–04970 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–1072; Docket No. CDC–2023–0017]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of Government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled STD Surveillance Network (SSuN). This information collection request is designed to strengthen national and local surveillance capacity for incident, new and emerging sexually transmitted diseases (STDs) by collecting relevant risk, demographic, and clinical information on patients at risk for STDs attending STD-related healthcare facilities, and providing more accurate estimates of the burden of disease, incidence of STDs, trends and impact of STDs at the population level.

DATES: CDC must receive written comments on or before May 9, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0017 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

The STD Surveillance Network (SSuN), (OMB Control No. 0920–1072, Exp. 10/31/2023)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting revision of the information collection entitled, The STD Surveillance Network (SSuN). Revisions to this submission include addition of mpox-related data elements for monitoring mpox risk, vaccination, diagnoses, and laboratory testing as part of ongoing surveillance for this emergent public health issue. Additionally, this Revision incorporates future expansion of SSuN to additional STD clinical facilities, addition of several new data elements to sentinel surveillance activities in STD clinical facilities related to Pre-Exposure Prophylaxis for HIV (PrEP), and enhanced investigations of a random sample syphilis cases reported to participating health departments. Multiple data elements associated with enhanced gonorrhea case investigations and provider reporting forms are also being retired.

The purpose of this project is to enhance national capacity for STD surveillance and better meet CDC's disease surveillance mandate by: (1) addressing gaps in epidemiologically-relevant information by providing more complete behavioral and demographic data on reported cases of notifiable STDs to enhance the ability of public health authorities to interpret trends in case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD

treatment and selected adverse health outcomes of STDs; (2) monitoring STD and HIV co-infection, screening, uptake of STD and HIV prevention interventions and health care access trends among patients seeking care for, and those diagnosed with, STDs in specialty clinical settings; and (3) providing a robust sentinel monitoring system for newly emergent and/or re-emergent health threats such as mpox.

Routine STD case surveillance activities are ongoing in all U.S. jurisdictions. Cases diagnosed in U.S. jurisdictions are voluntarily reported to CDC through the National Notifiable Diseases Surveillance System (NNDSS) and case data are collaboratively defined in cooperation with the Council of State and Territorial Epidemiologists (CSTE). However, case data received by CDC through NNDSS are increasingly missing required patient demographics and are extremely limited in scope with respect to risk behaviors, treatments prescribed, co-infection with other infections, preventive services, and sexual network characteristics. These data are needed to monitor incidence and prevalence and to inform prevention and control efforts.

Additionally, clinical information on patients seeking STD-specific care in specialty STD clinics is not available through any other national medical record abstracts or data sources. These data are critical to detecting emergent STD-related sequela or reemergence of mpox, appropriately informing local disease control activities and to inform analyses of national trends in the epidemiology of STD incidence. These data are also useful to monitor care services in essential safety-net STD clinics and evaluate local and national STD prevention and control measures. SSuN is the only surveillance infrastructure providing such comprehensive, representative information on patient and sex-partner characteristics, clinical presentation, STD screenings, uptake of HIV testing, screening for and uptake of mpox vaccine in STD clinics, curative and preventive treatment patterns, provider compliance with treatment recommendations, HIV co-infection among persons diagnosed with STDs and uptake of STD and HIV prevention interventions such as pre-exposure prophylaxis for HIV (PrEP) and/or Post-Exposure Prophylaxis (PEP) for bacterial STDs. These measures are key elements of the U.S. national strategy to End the HIV Epidemic (EHE) and support the Sexually Transmitted Infections, National Strategic Plan for the United States.

The STD Surveillance Network was established in 2005 as a network of six funded state and local public health agencies providing more comprehensive STD case-level and clinical facility information. In 2008, SSuN was expanded to 12 recipients to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. The network's activities were continued in a third funding cycle in 2013, with 10 recipients conducting core data collection activities in STD clinics and among a random sample of reported cases.

The current project, SSuN Cycle 4 (2019–2024), comprises 11 U.S. local/state health departments, including Baltimore City Health Department, California Department of Public Health, City of Columbus Public Health Department, Florida Department of Health, Indiana Department of Public Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, Utah Department of Public Health and Washington State Department of Health.

SSuN Cycle 4 continues to provide critical information addressing CDC's Division of Sexually Transmitted Disease (DSTDP) priorities as articulated in the STI National Strategic Plan, including contributing data to CDC's annual STD Surveillance Report, CDC's quarterly progress indicators and contributing to the body of literature related to STDs. Trend data across multiple cycles of SSuN are frequently used to inform policy discussions on prevention and treatment recommendations for common bacterial STDs. Of particular importance, SSuN provides data on use of pre- and post-exposure prophylaxis to prevent STDs and HIV infection (PEP and PrEP). SSuN also provides documentation of critical changes in clinical services provided by specialty STD clinics, and on the proportion of cases treated with appropriate antimicrobial regimens, an essential indicator of compliance with CDC treatment recommendations to combat the emergence of antimicrobial resistance (AMR). More recently, SSuN data have also been invaluable in assessing COVID–19 and mpox impacts on reported case incidence and patient access and care-seeking patterns and provides a reliable monitoring infrastructure for mpox re-emergence. STD clinics were the front-line provider of choice for persons suspecting mpox infection or seeking preventive services such as mpox vaccination.

Data collection components of SSuN are grouped into two primary strategies, reflecting different sentinel and enhanced population-based surveillance methods and activities. Strategy A includes sentinel surveillance in STD clinics to monitor patient care, screening and diagnostic practices, HIV co-infection, treatment and STD-related HIV prevention services delivered to patients. In collaboration with participating local/state health departments and their clinical partners, SSuN implements consensus protocols to collect demographic, clinical and risk behavior data on patients presenting for care in selected specialty STD clinics. Records for patients presenting for care are also matched to the jurisdiction's HIV surveillance registry, providing data on HIV co-infection not currently available from any other multi-jurisdictional source. Data for these activities are abstracted from existing electronic medical records at participating STD clinics, leveraging information that is already collected in the provision of routine STD clinical care. All records are fully de-identified by collaborating facilities or health departments and transmitted to CDC through secure file transport mechanisms six times annually. The estimated time for the clinic data managers to abstract/recode data is four hours every two months. The current revision anticipates expansion of this activity from the current 15 clinics to up to 40 STD clinics beginning in 2024 with a resulting burden of 960 hours (40 × 4 hours × 6 times/year).

The second core data collection activity, Strategy B, currently includes: (1) abstraction recoding and reporting of all gonorrhea and syphilis cases reported in the collaborating jurisdiction; (2) enhanced investigations on a random sample of all persons diagnosed with gonorrhea or syphilis; and (3) health department abstraction and registry matching for a complete census of reported gonorrhea and syphilis cases. For the first activity, a random sample of all gonorrhea cases diagnosed and reported to health departments within the participating jurisdictions are selected for enhanced investigations. Beginning in 2024, these investigations will be expanded to include a random sample of reported syphilis cases, include abstracting clinical data from diagnosing providers, matching cases with existing health department disease registries and brief patient demographic and behavioral interviews (10 minutes per response). The population of interest includes all persons diagnosed and reported with

gonorrhea and syphilis; existing case records are matched to other health department disease registries to determine co-infections and to document laboratory and treatment information known by the health department through routine case investigations and local laboratory reporting. In the proposed revision, syphilis cases will also be selected for enhanced provider and patient investigations utilizing the same consensus protocols used for enhanced gonorrhea case investigations. Considering recent increases in syphilis cases in the U.S., especially congenital syphilis, these data are critical to informing local and national syphilis prevention and control activities. SSuN recipients implement protocols providing uniformly coded data on demographic characteristics, behavioral risk factors, clinical care, laboratory data and health care seeking behaviors that are combined into a national dataset following data quality assurance at CDC.

In 2021, there were 211,791 cases of gonorrhea diagnosed and reported across the 11 current recipients of SSuN. Approximately 7.4%, or 15,715 cases were randomly sampled for enhanced investigation; full enhanced investigations were completed for 6,186 (39.4%). During the COVID–19 public health emergency, a slightly larger proportion of cases were lost to follow-up than in prior years due to local staffing shortages, issues with timely laboratory and case reporting, and higher than average patient refusals. No additional burden is anticipated from the future inclusion of early syphilis cases in Strategy B because of the decrease in gonorrhea case investigations.

Data managers at each of the local/state health departments or clinical facilities receiving funding are responsible for transmitting validated datasets for these activities to CDC every other month. This reflects 5,280 burden hours for Strategy A and B data management (11 respondents × 12 data transmissions × 40 hours per data transmission).

The total estimated annual burden hours for SSuN are 7,407. Respondents from local/state health departments and/or clinical facilities receive Federal funds to participate in this project. There are no costs to patients or respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
Data managers at STD clinics (Strategy A).	Electronic Clinical Record Abstraction.	40	6	4	960
General Public, Adults (sample of persons diagnosed and reported with gonorrhea and/or syphilis).	Patient interviews for a random sample of gonorrhea and syphilis cases.	7,000	1	10/60	1,167
Data Managers: 11 local/state health departments.	Data cleaning/validation, HIV-registry matching, data transmission.	11	12	40	5,280
Total					7,407

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–04972 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22ET]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Traveler-based Genomic Surveillance'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 6, 2022, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Traveler-based Genomic Surveillance—New—National Center for

Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Travelers' Health Branch (THB) requests three-year approval for information collection from international air travelers that participate in the Traveler-based Genomic Surveillance project. Genetic variants of SARS–CoV–2 have been emerging and circulating around the world throughout the COVID–19 pandemic. Of particular concern are variants for which there is evidence of an increase in transmissibility, more severe disease (for example, increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.

CDC recommends that all arriving international travelers get tested before departing and 3–5 days after travel. However, this testing is not mandatory for all travelers. Furthermore, there are currently few systems that conduct disease surveillance in the population of arriving international travelers. Moreover, as testing and sequencing for SARS–CoV–2 continue to decline worldwide, detecting emerging variants of concern (VOCs) in a timely manner is becoming more and more difficult.

To address this gap, in September 2021, the THB, in collaboration with private partners, implemented a voluntary SARS–CoV–2 genomic surveillance program with the goal of early detection of novel VOCs. Surveillance for new and emerging variant strains among travelers can provide researchers and public health officials critical time to collect information about the transmissibility, virulence, and effectiveness of existing vaccines, diagnostics, and therapeutics. The project is conducted with external partners and groups within DGMQ and across CDC, including the Office of Advanced Molecular Detection. The program began at New York's John F. Kennedy International Airport in September 2021 and later expanded to include Newark Liberty International, San Francisco International, and Hartsfield-Jackson Atlanta International airports. Since November 2022, the program has expanded to Los Angeles, Seattle, and Washington Dulles. Information collection for this project is currently approved under a Public Health Emergency PRA Waiver.

The information collection for which approval is sought is in accordance with CDC/DGMQ's mission to reduce morbidity and mortality among travelers and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. This mission is supported by the Section 361 of the Public Health Service Act regulations found in 42 Code of Federal Regulations part 70 and 71. Also supported under general authorities provided by Sections 301 and 311 in the Public Health Service Act regulations.

CDC requests OMB approval for an estimated 46,250 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Arriving international traveler	Questionnaire	555,000	1	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–04968 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE24–001, Panel B, Grants for Injury Control Research Centers (ICRC).

Dates: May 17–18, 2023.

Times: 8:30 a.m.–5 p.m., EDT.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE, Atlanta, Georgia 30346.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341; Telephone: (404) 639–6473; Email: *AWilkes@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. 2023–04923 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE24–001, Panel A, Grants for Injury Control Research Centers (ICRC).

Dates: May 16–17, 2023.

Times: 8:30 a.m.–5 p.m., EDT.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE, Atlanta, Georgia 30346.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Mikel Walters, Ph.D., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341; Telephone: (404) 639–0913; Email: *MWalters@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. 2023–04922 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–SIP23–001, Effective Community Conversations for Influenza and COVID–19 Vaccine Uptake; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–SIP23–001, Effective Community Conversations for Influenza and COVID–19 Vaccine Uptake; May 2, 2023, 11:00 a.m.–3:00 p.m., EDT, teleconference, in the original **Federal Register** Notice. The meeting was published in the **Federal Register** on February 13, 2023, Volume 88, Number 29, page 9289.

The meeting is being amended to change the meeting time and should read as follows:

Date: May 2, 2023

Time: 10 a.m.–6 p.m., EDT

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Catherine Barrett, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–3, Atlanta, Georgia 30341–3717; Telephone: (770) 718–7664; Email: *CBarrett@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. 2023–04918 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE23–005, Panel B, Research Grants to Inform Firearm-Related Violence and Injury Prevention Strategies (R01).

Dates: April 17–18, 2023.

Times: 8:30 a.m.–5 p.m., EDT.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE, Atlanta, Georgia 30346.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341; Telephone: (404) 639–6473; Email: *AWilkes@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. 2023–04920 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–0997; Docket No. CDC–2023–0016]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Standardized National Hypothesis Generating Questionnaire (NHGQ). This questionnaire collects exposure information from ill people involved in a suspected multistate foodborne outbreak, and aids public health investigators in identifying the potential source of infection.

DATES: CDC must receive written comments on or before May 9, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0016 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Standardized National Hypothesis Generating Questionnaire (SNHGQ) (OMB Control No. 0920–0997, Exp. 5/31/2023)—Revision—National Center for Emerging Zoonotic and Infectious Disease (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly one in six Americans get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the United States there is not a standard, national form or data collection system for illnesses caused by many enteric pathogens. Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.

CDC requests a revision to this project in order to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire (SNHGQ), from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint how and where contamination events occur.

The SNHGQ was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to collect core elements data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Since the last revision of the SNHGQ in 2019, CDC has investigated over 470 suspected multistate foodborne and enteric clusters of infection involving over 26,000 ill people. In these investigations, an outbreak vehicle has been identified in 199 cases. These outbreaks have led to many product recalls and countless regulatory actions that have removed millions of pounds of contaminated vehicles out of commerce. In almost all instances, the SNHGQ or

iterations of the SNHGQ have been instrumental in the successful investigation of these outbreaks. The questionnaire has allowed investigators to more efficiently and effectively interview ill persons as they are identified. Because these exposures are captured in a common, standard format, we have been able to share and analyze data rapidly across jurisdictional lines. Faster interview response and analysis times have allowed for more rapid epidemiologic investigation and quicker regulatory action, thus helping to prevent thousands of additional illnesses from occurring and spurring industry to adopt and implement new food safety measures in an effort to prevent future outbreaks.

CDC requests OMB approval for an estimated 3,000 annualized burden hours (approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak investigations with 45 minutes/response). There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Ill individuals identified as part of an outbreak investigation.	Standardized National Hypothesis Generating Questionnaire.	4,000	1	45/60	3,000
Total					3,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–04971 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE23–005, Panel A, Research Grants to Inform Firearm-Related Violence and Injury Prevention Strategies (R01).

Dates: April 17–18, 2023.

Times: 8:30 a.m.–5 p.m., EDT.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE, Atlanta, Georgia 30346.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Mikel Walters, Ph.D., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341; Telephone: (404) 639–0913; Email: *MWalters@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. 2023–04919 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; (SEP)—RFA–OH–22–005, Commercial Fishing Occupational Safety Research Cooperative Agreement; and RFA–OH–22–006, Commercial Fishing Occupational Safety Training Project Grants.

Date: May 17, 2023.

Time: 1 p.m.–5 p.m., EDT.

Place: Video-Assisted Meeting.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Dan Hartley, Ed.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505; Telephone: (304) 285–5812; Email: *DHartley@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. 2023–04924 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE23–006, Research Grants to Rigorously Evaluate Innovative and Promising Strategies to Prevent Firearm-Related Violence and Injuries (R01).

Dates: April 19–20, 2023.

Times: 8:30 a.m.–5 p.m., EDT.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE, Atlanta, Georgia 30346.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341; Telephone: (404) 639–6473; Email: *AWilkes@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. 2023–04921 Filed 3–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10728 and CMS–416]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 9, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *https://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10728 Value in Opioid Use Disorder Treatment Demonstration

CMS–416 Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Value in Opioid

Use Disorder Treatment Demonstration; *Use:* Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act), which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to ''increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures.'' As required by statute, Value in Treatment was implemented January 1, 2021. Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary.

Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and performance-based incentive payments under the Value in Treatment program, each participant shall report data necessary to: monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the performance-based incentive payment. *Form Number:* CMS–10728 (OMB control number: 0938–1388); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 388; *Total Annual Responses:* 388; *Total Annual Hours:* 282. (For policy questions regarding this collection contact Rebecca VanAmburg at 410–786–0524.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; *Use:* The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. *Form Number:* CMS–416 (OMB control number 0938–0354); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,512. For policy questions regarding this collection contact Mary Beth Hance at 410–786–4299.

Dated: March 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–04890 Filed 3–9–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–437A & CMS–437B and CMS–10836]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by April 10, 2023.

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Rehabilitation Unit and Hospital Criteria Worksheet; *Use:* Inpatient Rehabilitation Facility (IRF) hospitals and units must initially attest that they meet the Inpatient Prospective Payment System (IPPS) exclusion criteria set forth at 42 CFR 412.20 to 412.29 prior to being placed into IPPS exempt status. Form CMS–437A must be completed by IRF units and form CMS–437B must be completed by IRF hospitals.

For first time verification requests for exclusion from the IPPS, an IRF unit or hospital must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new IRF units or hospitals must provide written certification that

the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. The completed CMS–437A and 437B forms are submitted to the State Agency (SA) no later than 5 months before the date the IRF unit or hospital would become subject to Inpatient Rehabilitation Facility Prospective Payment System (IRF–PPS). For IRF units and hospitals already excluded from the IPPS, annual onsite re-verification surveys by the SA are no longer required. IRF units and hospitals must now re-attest to meeting the exclusion criteria every 3 years thereafter.

IRF units and hospitals that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. For the tri-annual re-verification, IRF units and hospitals will be provided with a copy of the appropriate CMS–437 worksheet at least 5-months prior to the beginning of its cost reporting period, so that the IRF unit or hospital official may complete and sign an attestation statement and complete and return the appropriate form CMS–437A or CMS–437B at least 5-months prior to the beginning of the cost reporting period. However, Fiscal Intermediaries (FIs) will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for IRF units and hospitals through a sample of medical records and the SA will verify the medical director requirement.

The SA will notify the RO at least 60 days prior to the end of the IRF unit's or hospital's cost reporting period of the status of compliance or non-compliance with the payment requirements. The information collected on the 437A and 437B forms, along with other information submitted by the IRF is necessary for determining the IRF's IPPS exclusion status. We have revised the CMS–437A and 437B forms so that they more adequately reflect the regulatory requirements of § 412.20 to § 412.29. More specifically, we have updated the text in the 3rd column of the form, which tells the facility what actions must be taken and what information must be verified to receive IPPS excluded status. Subsequent to publication of the 60-day **Federal Register** notice (87 FR 48482) and notice extending the comment period for the 60-day notice (87 FR 61333), the collection instrument was revised to correct errors in the guidance and verification requirements sections of the forms. *Form Number:* CMS–437A and CMS–437B (OMB control number: 0938–0986); *Frequency:* tri-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 497; *Total Annual Responses:* 497; *Total Annual Hours:* 497. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705).

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicare Plan Performance Warning Information; *Use:* The Centers for Medicare & Medicaid Services (CMS) is seeking approval to collect information to assist in the Agency's response to two reports from the Department of Health and Human Services Office of the Inspector General (OIG) related to how the agency conveys information on plan performance.

CMS is conducting this research to respond to OIG's recommendations related to sharing additional information with beneficiaries on plan performance in a clear and accessible format, particularly related to information which may warn or caution beneficiaries about plan performance issues. CMS is seeking to learn more about how beneficiaries, caregivers, and the intermediaries who assist them use and understand the information CMS currently makes (or may make) available, as well as to assess their interest in accessing this information. *Form number:* CMS–10836 (OMB control number: 0938–New); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 288; *Number of Responses:* 288; *Total Burden Hours:* 561 (For questions regarding this collection contact Elizabeth Goldstein at 443 845–6993).

Dated: March 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–04889 Filed 3–9–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10834]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 9, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____ Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10834 Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; *Use:* Section 2003 of the SUPPORT for Patients and Communities Act of 2018 requires that prescribing of a Schedule II, III, IV, and V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the calendar year (CY) 2021 and 2022 Physician Fee Schedule (PFS) final rules, CMS finalized the electronic prescribing for controlled substances (EPCS) requirements and exceptions at 42 CFR 423.160(a)(5). Compliance for prescribers not in long-term care facilities begins in CY 2023. Compliance for prescribers in long-term care facilities begins in CY 2025.

EPCS requirements do not require prescribers or pharmacies to submit additional data to CMS; however, CMS did finalize one exception that requires data collection. The EPCS exception, at § 423.160(a)(5)(iv), requires a prescriber to apply for a waiver if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. This collection of information is necessary to provide adequate and timely exception from the EPCS requirements if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. *Form Number:* CMS–10834 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions), and Public sector (State, Local or Tribal Governments); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 17. (For policy questions regarding this collection contact Mei Zhang at (410) 786–7837).

Dated: March 7, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–04935 Filed 3–9–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; National Communication System for Runaway and Homeless Youth, Currently Operated by the National Runaway Safeline (NRS) Data Collection (New Collection)

AGENCY: Family and Youth Services Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Family and Youth Services Bureau's (FYSB) Runaway and Homeless Youth Division has a legislative requirement to fund a National Communication System, which is currently operated by the National Runaway Safeline (NRS). The NRS provides information, referral services, crisis intervention, and prevention resources to vulnerable youth at risk of running away and/or becoming homeless and their families or legal guardians at no cost. When necessary, the NRS refers runaway and homeless youth to shelters, counseling, medical assistance, and other vital services. The NRS collects information from all contacts with youth and adults connecting with the NRS (*i.e.,* parents, family members, legal guardians, service providers) on a voluntary basis to inform crisis services and develop an annual report on the information collected during calls, chats, emails, and forum posts from young people who reached out to the NRS's crisis services.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NRS is required to have a system for collecting and analyzing data to report on calls, emails, chat, texts, and online messages received as well as other information, such as prevention resources, referrals, demographics, and visitors to the NRS website. The NRS must submit monthly and semi-annual reports that include the following:

- Number of calls received, answered, and missed.
- Number of chats, emails, and texts received; number of chats, emails, and texts answered; and number of chats, emails, and texts that were missed and did not receive a response, in which the users are youth in crisis, runaway youth, and youth experiencing homelessness.
- Number of parents, legal guardians, and service providers contacting the NRS and the type of resources, interventions, and technical support/assistance requested and provided.
- Number and type of prevention materials disseminated to communities, especially to underserved populations.
- Number and type of unique visitors to the NRS' website.
- Information on referrals provided and where youth were referred for services.
- Information on the callers' or users' demographics and where they were located when contacting the NRS.

• Information on the prevention materials developed and disseminated by the NRS.

• Information and analysis of the latest trends and their impact on runaway prevention.

The NRS will use two forms, one form to collect relevant information disclosed during calls, emails, and forum posts and a second form to collect information from chats. All data will be provided to FYSB in the aggregate and no personally identifiable data are collected.

The information collected will allow FYSB to better understand the types of services needed by youth contacting the NRS, as well as to identify outreach and prevention strategies to increase the visibility of the NRS services among youth experiencing housing instability, homelessness, youth who run away, and youth in crisis. Additionally, the findings from this data collection will be included in a required Report to Congress to provide relevant and up-to-date information on the status of youth in crisis and runaway and homeless youth nationwide.

Respondents: Youth and adults who contact the National Runaway Safeline during calls, chats, emails, and forum posts.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Youth in Crisis Form	47,175	1	.23	10,850	3,617
NRS Live Chat Form	29,679	1	.65	19,291	6,430

Estimated Total Annual Burden Hours: 10,047.

Authority: Section 331 of the Runaway and Homeless Youth Act authorizes the award of grants for the National Communication System for Runaway and Homeless Youth (34 U.S.C. 11231).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–04992 Filed 3–9–23; 8:45 am]

BILLING CODE 4182–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Office of Refugee Resettlement Unaccompanied Refugee Minors Program Application and Withdrawal of Application or Declination of Placement Form (OMB #0970–0550)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR) is requesting a three-year extension with revisions of the Unaccompanied Refugee Minors (URM) Program Application and Withdrawal of Application or Declination of Placement Form (OMB #0970–0550, expiration 08/31/2023). Proposed revisions include additional instructions, a small number of new questions, dropping a few questions, and rephrasing existing questions.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The URM Program Application is completed on behalf of unaccompanied children in the United States who are applying for entry into the URM Program. The application includes biographical data and information on the child's needs to support placement efforts. The Withdrawal of Application or Declination of Placement Form is completed when a child is no longer interested in entering the URM Program or is not interested in entering the placement they were offered.

Respondents: Case managers, attorneys, or other representatives working with unaccompanied children who are eligible for the URM Program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Unaccompanied Refugee Minors Program Application	450	3	1.5	2,025	675
Withdrawal of Application or Declination of Placement Form	50	3	0.2	30	10

Estimated Total Annual Burden Hours: 685.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 8 U.S.C. 1522(d).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–04987 Filed 3–9–23; 8:45 am]

BILLING CODE 4184–89–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3351]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Cepheid. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of February 10, 2023.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. Notice of the Secretary's determination was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on September 13, 2022 (87 FR 56074). On February 10, 2023, having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA issued an EUA to Cepheid for the Xpert Mpox, subject to the terms of the Authorization. The Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent revision to the Authorization can be found on FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

February 10, 2023

Rachel Doran, Ph.D.
Senior Regulatory Affairs Specialist
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Device:	Xpert Mpox
EUA Number:	EUA220483
Company:	Cepheid
Indication:	This test is authorized for the qualitative detection of DNA from monkeypox virus clade II[1] and non-variola *Orthopoxvirus* in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of mpox[2] by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing on the GeneXpert Dx and GeneXpert Infinity instruments is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests. Testing on the GeneXpert Xpress (Hub Configuration) instrument is limited to laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. Testing on the GeneXpert Xpress (Hub Configuration) instrument is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

[1] On August 12, 2022, following a meeting convened by the World Health Organization (WHO) monkeypox virus variants were renamed to align with current best practices under the International Classification of Diseases and the WHO Family of International Health Related Classifications (WHO-FIC). This letter will refer to the former West African clade as clade two (II). Refer to: https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names.

[2] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term "mpox" as a synonym for monkeypox, the disease cause by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

Dear Dr. Doran:

This letter is in response to your[3] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of United States citizens living abroad that involves monkeypox virus.[5] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "Xpert Mpox Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity Systems" and "Xpert Mpox Instructions for Use - For Use with GeneXpert Xpress System (point of care system)." There is an FDA-cleared test for the qualitative detection of non-variola *Orthopoxvirus*, that includes monkeypox virus, but this is not an adequate and available alternative to your product.[7]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The monkeypox virus can cause a serious or life-threatening disease or condition, to humans infected by this virus;

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[3] For ease of reference, this letter will use the term "you" and related terms to refer to Cepheid.

[4] For ease of reference, this letter will use the term "your product" to refer to the Xpert Mpox used for the indication identified above.

[5] 87 FR 50090 (August 15, 2022)

[6] 87 FR 56074 (September 13, 2022)

[7] To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558) is the only test available in the United States with FDA clearance for the detection of non-variola *Orthopoxvirus* DNA, including vaccinia, cowpox, monkeypox and ectromelia viruses at varying concentrations. Available information indicates that timely detection of mpox cases in the United States requires wide availability of diagnostic testing to control the spread of this contagious infection and there is currently a need for additional diagnostic testing for monkeypox virus in the United States.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, and that the known and potential benefits of your product when used for diagnosing infection with the monkeypox virus, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[8]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a real-time PCR test intended for the qualitative detection of DNA from monkeypox virus clade II and non-variola *Orthopoxvirus* DNA in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of mpox by their healthcare provider.

Testing on the GeneXpert Dx and GeneXpert Infinity instruments is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests. Testing on the GeneXpert Xpress (Hub Configuration) instrument is limited to laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. Testing on the GeneXpert Xpress (Hub Configuration) instrument is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of monkeypox virus (clade II) and non-variola *Orthopoxvirus* DNA which are generally detectable in human pustular or vesicular lesion specimens during the acute phase of infection. Positive results are indicative of the presence of monkeypox virus (clade II) and/or non-variola *Orthopoxvirus* DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results obtained with this device do not preclude monkeypox virus (clade II) and/or non-variola *Orthopoxvirus* infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Your product, when used with the applicable authorized systems automates all aspects of nucleic acid testing including sample preparation, nucleic acid extraction and amplification, and detection of the monkeypox virus (clade II) and non-variola *Orthopoxvirus* nucleic acid targeted

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

sequences using real-time (RT) PCR assays in a single-use cartridge as described in the authorized labeling (described below). The Xpert Mpox includes the materials (or other authorized materials as may be requested under Condition O. below) described in both of the Instructions for Use.

Your product requires control materials (or other authorized control materials as may be requested under Condition O. below) that are described in both of the Instructions for Use. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the authorized labeling described below.

The labeling entitled "Xpert Mpox Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity Systems," "Xpert Mpox Instructions for Use - For Use with GeneXpert Xpress System (point of care system)," "Quick Reference Instructions Xpert Mpox and the GeneXpert Xpress System (Hub configuration)," and "Xpert Mpox (EUA) Documentation and ADF" flyer (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), and the following fact sheets pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Cepheid – Xpert Mpox
- Fact Sheet for Patients: Cepheid – Xpert Mpox

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the

circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Cepheid (You) and Authorized Distributor(s)[9]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. Your product must comply with the following quality system requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

E. You and authorized distributor(s) must include a physical copy of the authorized "Xpert Mpox (EUA) Documentation and ADF" flyer and the "Quick Reference Instructions Xpert Mpox and the GeneXpert Xpress System (Hub configuration)" with each shipped product to authorized laboratories, and must make the authorized "Xpert

[9] "Authorized Distributor(s)" are identified by you, Cepheid, in your EUA submission as an entity allowed to distribute your product.

Mpox Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity Systems," and the "Xpert Mpox Instructions for Use - For Use with GeneXpert Xpress System (point of care system)," electronically available with the opportunity to request copies in paper form, and after such request, you must promptly provide the requested information without additional cost.

F. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which your product is distributed and the number of your product distributed.

H. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov).

I. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Cepheid (You)

J. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

K. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

L. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

M. If requested by FDA, you must submit associated documents and records related to your quality system for FDA review within 48 hours of the request.

N. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

O. You may request modifications to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such

additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for modification to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA.

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

R. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) if requested by FDA.[10] After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

S. You must have a process in place to track adverse and report to FDA pursuant to 21 CFR Part 803.

T. You must evaluate the impact of monkeypox viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

V. If requested by FDA, you must further evaluate the clinical performance of your product using fresh natural clinical specimens in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

[10] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

W. You must submit to DMD/OHT7/OPEQ/CDRH within 3 months of the date of this letter your plan and anticipated timeline to establish and maintain a quality system that is appropriate for your product's design and manufacture, and that meets the requirements of either the 2016 edition of ISO 13485 or 21 CFR Part 820.

Authorized Laboratories

X. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Y. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Z. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

AA. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

BB. Authorized laboratories must have a process in place to track adverse events and report to you (Cepheid Customer Technical Support +1-888-838 3222) and to FDA pursuant to 21 CFR Part 803.

CC. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling your product, and use your product in accordance with the authorized labeling.

Cepheid (You), Authorized Distributor(s) and Authorized Laboratories

DD. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (via email: +1-888-838-3222 or techsupport@cepheid.com).

EE. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

FF. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

GG. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

HH. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

Dated: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04934 Filed 3–9–23; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from December 7, 2022, through February 24, 2023, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- OnsiteGene, Inc.'s Hi-Sense COVID–19 Molecular Testing Kit 1.0, issued December 19, 2022;
- CTK Biotech, Inc.'s ImmuView COVID–19 Antigen Home Test, issued December 20, 2022;
- Advin Biotech, Inc.'s Advin COVID–19 Antigen Test @Home, issued December 22, 2022;
- Oceanit Foundry LLC's ASSURE–100 Rapid COVID–19 Home Test, issued December 22, 2022;
- ADL Diagnostics, Inc.'s (dba Anavasi Diagnostics) The AscencioDx COVID–19 Test and The AscencioDx Molecular Detector, issued February 8, 2023;
- The HFI Laboratory at Boston University's (dba the BU Clinical Testing Laboratory) BU SARS–CoV–2 Test, issued February 8, 2023;
- GenBody, Inc.'s GenBody COVID–19 Ag Home Test, issued February 17, 2023; and
- Mologic, Inc.'s COVI–Go SARS–CoV–2 Ag Self-Test, issued February 22, 2023.

FDA is hereby announcing the following Authorizations for multianalyte tests:

- Visby Medical, Inc.'s Visby Medical Respiratory Health Test, issued December 23, 2022; [4]
- Becton, Dickinson and Company's BD Respiratory Viral Panel for BD MAX System, issued February 3, 2023; [5]
- LumiraDx UK Ltd.'s LumiraDx SARS–CoV–2 & Flu A/B RNA STAR Complete Assay, issued February 3, 2023; [6] and
- Lucira Health, Inc.'s Lucira COVID–19 & Flu Home Test, issued February 24, 2023.[7]

Dated: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04931 Filed 3–9–23; 8:45 am]

BILLING CODE 4164–01–P

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[5] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, influenza B virus and/or RSV nucleic acid, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[7] As set forth in the EUA for this product, FDA has concluded that: (1) The SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA Grantee Customer Satisfaction Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than May 9, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: HRSA Grantee Customer Satisfaction Survey, OMB No. 0906–0006—REVISION.

Abstract: The Office of Federal Assistance Management within HRSA plans to survey HRSA grant recipients to better understand their opinions about HRSA's grants processes and to improve the way HRSA conducts business with them. This survey will focus on grantee customer satisfaction areas related to the grants life cycle, grantee relationships with HRSA staff (*e.g.,* Project Officers, Grants Management Officers), technical assistance received from HRSA Bureaus and Offices, availability of grant resources, and grantee access to guidance and instructional documents, etc. The seven grants management areas, which are directly related to the grants life cycle, are: Customer Service/Cooperation; Policies and Procedures; Pre-Award Phase; Award Phase; Reporting/Post-Award Administration; Technical Assistance; and Priorities for Improvement. Receiving this information from external customers will provide HRSA with a repository of information that will be incorporated into strategic efforts to improve grants management services and customer service.

Need and Proposed Use of the Information: The HRSA Grantee Customer Satisfaction Survey will provide meaningful and relevant results to agency decision-makers about various customer satisfaction domains (*e.g.,* efficiency, timeliness, usefulness, responsiveness, quality of and overall satisfaction with HRSA project officers, products, and services). The information collected will assist HRSA in its efforts to gauge, understand, and effectively respond to the needs and concerns of its customers, especially as they relate to the aforementioned areas. The survey results will provide HRSA with concrete indicators regarding the best areas in which to dedicate resources to improve customer service. This information will be used to support agency-wide continuous quality improvement efforts. Survey results will also be used by HRSA to improve the efficiency, quality, and timeliness of its grants business processes, as well as to strengthen its partnership with external customers.

Likely Respondents: HRSA grantees, specifically individuals who hold positions as a grantee's Grant Administrator, Business Officer, or Project Director/Principal Investigators, etc.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses *	Average burden per response (in hours)	Total burden hours
HRSA Grants Management Customer Satisfaction Survey	3,690	1	1,180	0.25	295
Total	3,690	1	1,180	0.25	295

* The Survey will be sent to 3,690 grantee organization contacts. Based on HRSA Customer Grantee Satisfaction Surveys administered in previous years, HRSA estimates a 32 percent response rate.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–04863 Filed 3–9–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as

amended, notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting Website (*http://videocast.nih.gov/*).

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: March 21, 2023.

Time: 1:00 p.m. to 4:45 p.m.

Agenda: Director's Report; RFA, RFP, and PAR Concept Reviews; and Scientific Presentations.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: BSA: *http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm,* where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 7, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–04967 Filed 3–9–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: April 24, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: Department of Bioethics Presentations, Interviews and other business of the Board.

Place: Clinical Center, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: April 25, 2023.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: Department of Bioethics Presentations, Interviews and other business of the Board.

Place: Clinical Center, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ronald Neumann, MD, Deputy Science Director, Clinical Center, National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, 301–496–6455, *rneumann@cc.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: March 6, 2023.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–04885 Filed 3–9–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cellular and Molecular Immunology.

Date: April 7, 2023.

Time: 1:00 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.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Pathogenic Eukaryotes.

Date: April 18, 2023.

Time: 11:00 a.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: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805–P, Bethesda, MD 20892, (301) 435–0000, *drammehbs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurobiology of Visual Processing and Multisensory Integration.

Date: April 25, 2023.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Janita N. Turchi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–4005, *turchij@mail.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: March 6, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–04907 Filed 3–9–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on April 25, 2023, 9 a.m.–4:30 p.m. (EDT).

The meeting is open to the public and will include consideration of minutes from the SAMHSA CSAT NAC meeting of August 30, 2022, a discussion with SAMHSA leadership, a discussion on Hepatitis C Elimination, a discussion on recent policy changes impacting substance use disorder care, including sections 1262 and 1263 of the Consolidated Appropriations Act of 2023 (commonly known as the Mainstreaming Addiction Treatment (MAT) and Medication Access and Training Expansion (MATE) Act provisions, respectively), and a discussion on Low Barrier Models for Medication for Opioid Use Disorder (MOUD). It will also cover updates on CSAT activities from the Office of the Director (OD); the Division of Pharmacologic Therapies (DPT); the Division of States and Community Systems (DSCS); the Division of Services Improvement (DSI); Office of Program Analysis and Coordination (OPAC); Office of Performance Analysis and Management (OPAM).

The meeting will be held at SAMHSA, 5600 Fishers Lane, 5E49, Rockville, MD 20857. Attendance by the public will be limited to space available and will be limited to the open sessions of the meeting. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person, Tracy Goss, CSAT NAC Designated Federal Officer (DFO) on or before April 14, 2023. Up two minutes will be allotted for each public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record.

The open meeting session may also be accessed virtually. Please register on-line at *https://snacregister.samhsa.gov,* to attend on either on site or virtually, submit written or brief oral comments, or request special accommodations for persons with disabilities. To communicate with the CSAT NAC DFO please see the contract information below.

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at *https://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council,* or by contacting the DFO.

Council Name: SAMHSA's Center for Substance Abuse Treatment, National Advisory Council.

Date/Time/Type: April 25, 9:00 a.m.–4:30 p.m. EDT, Open.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–0759, Email: *tracy.goss@samhsa.hhs.gov.*

Dated: March 6, 2023.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2023–04887 Filed 3–9–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–0351]

Consolidated Port Approaches Port Access Route Studies (CPAPARS)

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of an update to the Consolidated Port Approaches Port Access Route Studies (CPAPARS). The Coast Guard is publishing this updated report to provide continued transparency on the consolidated recommendations and alternatives provided by the supplemental PARS, the Advance Notice of Proposed Rulemaking and ongoing dialogue with the maritime industry.

DATES: Comments must be submitted to the online docket via *https://www.regulations.gov* on or before June 8, 2023.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Maureen Kallgren, Coast Guard; telephone 202–372–1561, email *maureen.r.kallgren2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background

Atlantic Coast Port Access Route Study

On April 5, 2017, the Coast Guard announced the completion of the Atlantic Coast Port Access Route Study in the **Federal Register** (82 FR 16510), which is available for viewing and download from the Coast Guard Navigation Center's website at *https://www.navcen.uscg.gov/port-access-route-studies.*

The ACPARS identified navigation safety corridors along the Atlantic Coast based on the predominant two-way vessel traffic and customary routes confirmed with AIS data for offshore deep draft and coastal seagoing tug/tow vessels. The study recommended using these corridor locations to establish shipping safety fairways or other appropriate vessel routing measures.

Based on the recommendations provided in the ACPARS, the Coast Guard published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** (85 FR 37034) on June 19, 2020. This ANPRM, which is available for viewing and download from the **Federal Register** docket USCG–2019–0279 at *www.regulations.gov,* sought comments regarding the possible establishment of fairways along the Atlantic Coast of the United States, as identified in the ACPARS final report.

Port Approaches and International Entry and Departure Transit Areas

Recognizing the ACPARS only analyzed coastal, longshore, and predominantly north/south vessel transit routes along the Atlantic Coast, the Coast Guard announced on March 15, 2019, new studies focused on port approaches and international entry and departure areas along the Atlantic Coast to supplement the ACPARS. On September 9, 2022, the Coast Guard announced the availability of the Consolidated Port Approaches and International Entry and Departure Transit Areas Port Access Route Studies, (CPAPARS). The CPAPARS summarizes the findings of four regional port access route studies: the Northern New York Bight; Seacoast of New Jersey Including Offshore Approaches to the

Delaware Bay, Delaware; Approaches to the Chesapeake Bay, Virginia; and the Seacoast of North Carolina; as well as ongoing dialogue with the maritime industry. Through continued engagement with stakeholders, the Coast Guard was notified of two erroneous graphics published in the report. Additionally, stakeholders sought clarification on some fairways adjustments and requested the opportunity to provide comments. This update corrects the graphical errors, amends certain recommended fairways, provides additional explanation of the recommendations, and provides a 90-day comment period. The updated CPAPARS has been completed and has been uploaded to the docket and at *https://www.navcen.uscg.gov/port-access-route-study-reports* for public review.

This notice is issued under authority of 46 U.S.C. 70003(c).

Dated: March 7, 2023.

Michael D. Emerson,

Director, Marine Transportation Systems.

[FR Doc. 2023–04997 Filed 3–9–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7077–N–06]

Privacy Act of 1974; Matching Program

AGENCY: Office of Administration, HUD.

ACTION: Notice of new matching program.

SUMMARY: Pursuant to the Privacy Act of 1974, as amended by the Computer Matching and Privacy Act of 1988 and the Computer Matching and Privacy Protections Amendment of 1990 (Privacy Act), and Office of Management and Budget (OMB) guidance on the conduct of matching programs, notice is hereby given of the establishment of a matching program between the U.S. Department of Housing and Urban Development (HUD) and the state of Iowa, the state of California, the state of Louisiana, and the Commonwealth of the Northern Mariana Islands (CNMI).

DATES: Please submit comments on or before April 10, 2023. The matching program will be effective on April 10, 2023 unless comments have been received from interested members of the public that require modification and republication of the notice. The matching program will continue for 18 months from the beginning date and may be extended an additional 12 months if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Interested persons are invited to submit comments regarding this notice at *www.regulations.gov* or to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10110, Washington, DC 20410. Communications should refer to the above docket number. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: To obtain additional information about this matching program and the contents of this Computer Matching Agreement between HUD and the state of Iowa, the state of California, the state of Louisiana, and the CNMI, please view this Computer Matching Agreement at the following website: *https://www.hud.gov/program_offices/officeofadministration/privacy_act/cma*.

For general questions about this matching program, contact Tennille Smith Parker, Director, Office of Disaster Recovery, U.S. Department of Housing and Urban Development, 451 7th Street SW, Room 7282, Washington, DC 20410, telephone number 202–708–3587. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs*. Facsimile inquiries may be sent to Ms. Parker at 202–708–0033. (Except for the''800'' number, these telephone numbers are not toll-free.) Email inquiries may be sent to *disaster_recovery@hud.gov*.

SUPPLEMENTARY INFORMATION: HUD is providing this notice in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101–508) (Privacy Act); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–108, 81 FR 94424 (December 23, 2016).

To support the prevention and detection of duplication of benefits, HUD will request data from FEMA on an as-needed basis to share with Community Development Block Grant disaster recovery (CDBG–DR) grantees, and the grantees will use the data to detect and prevent the duplication of benefits. CDBG–DR grantees will conduct a duplication of benefits review for CDBG–DR grant-funded programs and activities. HUD's data request will be based on the specific program requirements specified in an approved CDBG–DR grantee action plan. CDBG–DR grantees will use FEMA data received through HUD to facilitate expedited program implementation while preventing the duplication of benefits already received from FEMA. All data sharing from HUD to CDBG–DR grantees will occur in accordance with agreements between HUD and the CDBG–DR grantees that address requirements related to the use and protection of the data.

Participating Agencies: U.S. Department of Housing and Urban Development (HUD), the state of Iowa, the state of California, the state of Louisiana, and the Commonwealth of the Northern Mariana Islands (CNMI).

Authority for Conducting the Matching Program: A. Robert T. Stafford Disaster Relief and Emergency Assistance Act (as amended at 42 U.S.C. 5155(a) *et seq.*) (Stafford Act), section 312, which requires each federal agency that administers any program providing financial assistance because of a major disaster or emergency to assure that no individual or entity receives duplicate financial assistance under any program, from insurance, or through any other source. The Stafford Act, 42 U.S.C. 5155(c), requires FEMA or HUD (whichever agency provided the duplicative assistance) to recover all duplicative assistance from the recipient when the head of such agency considers it to be in the best interest of the Federal Government.

B. Section 408(i) of the Stafford Act, 42 U.S.C. 5174(i), directs and authorizes FEMA, in carrying out Section 408 (Federal Assistance to Individuals and Households), to ''develop a system, including an electronic database,'' to: (a) Verify the identity and address of recipients of assistance to provide reasonable assurance that payments are made only to an individual or household that is eligible for such assistance, (b) Minimize the risk of making duplicative payments or payments for fraudulent claims, (c) Collect any duplicate payment on a claim or reduce the amount of subsequent payments to offset the amount of any such duplicate payment, (d) Provide instructions to recipients of assistance regarding the proper use of any such assistance, regardless of how such assistance is distributed, and (e) Conduct an expedited and simplified

review and appeal process for an individual or household whose application for assistance is denied.

C. HUD imposes the requirements of the Stafford Act, section 312, on CDBG–DR grantees. Appropriations acts making CDBG–DR funds available, as listed in Section II.C.8 of the Computer Matching Agreement, require CDBG–DR grantees to have adequate procedures to prevent the duplication of benefits. HUD enforces these requirements on CDBG–DR grantees using its statutory and regulatory remedies for noncompliance in Section 111 of Title I of the Housing and Community Development of 1974 (42 U.S.C. 5311) and regulations at 24 CFR part 570 and 2 CFR part 200.

D. Executive Order 13411, ''Improving Assistance for Disaster Victims,'' 71 FR 52729 (August 29, 2006), calls on federal agencies to ''reduce unnecessarily duplicative application forms and processes for Federal disaster assistance,'' which includes processing benefits applications submitted by individuals, businesses, or other entities for the same disaster.

E. The President may authorize both emergency sheltering and Section 408 federal assistance to individuals and households, pursuant to either a major disaster under Section 403, at 42 U.S.C. 5170b, or an emergency under Section 502 of the Stafford Act, 42 U.S.C. 5192. Essential Assistance, pursuant to Section 403(a)(3)(B) of the Stafford Act, 42 U.S.C. 5170b, authorizes emergency sheltering, including both congregate and non-congregate sheltering, to meet the immediate needs of disaster survivors for a major disaster. Additionally, federal assistance where necessary to prevent human suffering under Section 502(a)(8) authorizes emergency sheltering for an emergency.

F. The Debt Collection Improvement Act of 1996, 31 U.S.C. 3325(d) and 7701(c)(1), which requires federal agencies to collect the Taxpayer Identification Number (TIN) or Social Security Number (SSN) of each person who receives payments from the Federal Government; and each person doing business with the Federal Government is required to furnish his or her TIN. For the purposes of 31 U.S.C. 7701, a person is doing business with the Federal Government if the person is: (1) A lender or servicer in a federal guaranteed or insured loan program administered by a federal agency, (2) An applicant for, or recipient of, a federal license permit, right-of-way, grant, or benefit payment administered by a federal agency, (3) A contractor of a federal agency, (4) Assessed a fine, fee, royalty, or penalty by a federal agency, or (5) In a relationship with a federal agency that may give rise to a receivable due to that agency such as a partner of a borrower in or a guarantor of a federal direct or insured loan administered by the federal agency. Each federal agency must inform each person required to disclose his or her TIN of the agency's intent to use such number for purposes of collecting and reporting on any delinquent amounts arising out of such person's relationship with the Federal Government.

G. The appropriations acts that authorize and appropriate supplemental CDBG–DR assistance lay out specific requirements, some of which may vary by appropriation. These appropriations acts impose requirements related to the (1) prevention of fraud, waste, and abuse, (2) order of assistance, and (3) prevention of duplication of benefits on HUD or its CDBG–DR grantees, as directed by the applicable act. The appropriations acts, listed below, also require HUD to make allocations based on a determination of unmet need in the ''most impacted and distressed areas'' resulting from major disasters.

Legal authority for CDBG–DR assistance is derived from Title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*); subsequent appropriations acts making CDBG–DR assistance available; the following prior appropriations acts—Public Law 117–180, 117–43, 116–20, 115–254, 115–123, 115–56, 115–31, 114–254, 114–223, 114–113, 113–2, 112–55, 111–212, 110–329, 110–252, 110–116, 109–234, 109–148, 108–324, 107–206, 107–117, 107–73, 107–38, 106–31, 105–277, 105–276, 105–174, 105–18, 104–134, 104–19, 103–327, 103–211, 103–75, and 103–50—and by the notices published in the **Federal Register** that govern CDBG–DR grant assistance including the *Updates to Duplication of Benefits Requirements Under the Stafford Act for Community Development Block Grant (CDBG) Disaster Recovery Grantees* at 84 FR 28836 (June 20, 2019).

H. The HUD regulation at 24 CFR 982.352(c) prohibits a family from receiving the benefit of Section 8 tenant-based assistance under the Housing Choice Voucher Program while also receiving the benefit of any of the following forms of other housing subsidy for the same or a different unit:

1. Public or Indian housing assistance,
2. Section 8 assistance (including other tenant-based assistance) under Section 8 of the U.S. Housing Act of 1937, 42 U.S.C. 1437f,
3. Assistance under former Section 23 of the United States Housing Act of 1937 (before amendment by the Housing and Community Development Act of 1974),
4. Section 101 of the Housing and Urban Development Act of 1965, 12 U.S.C.1701s (Section 101 rent supplements),
5. Section 236 of the National Housing Act, 12 U.S.C.1715z–1 (Section 236 rental assistance payments),
6. Tenant-based assistance under the HOME Investment Partnerships Program (HOME) authorized by Title II of the Cranston-Gonzalez National Affordable Housing Act, 42 U.S.C. 12701 *et seq.,*
7. Rental assistance payments under Section 521 of the Housing Act of 1949, 42 U.S.C. 258 1441 *et seq.* (a program of the Rural Development Administration),
8. Any local or state rent subsidy,
9. Section 202 of the Housing Act of 1959, 12 U.S.C. 1701q, as amended (Section 202 supportive housing for the elderly),
10. Section 811 of the Cranston-Gonzalez National Affordable Housing Act, as amended, 42 U.S.C. 8013 (Section 811 supportive housing for persons with disabilities),
11. Section 202 projects for non-elderly persons with disabilities (Section 162 assistance) authorized by Section 162 of the Housing and Community Development Act of 1987, 12 U.S.C. 1701a note, amending Section 202(h) of the Housing Act of 1959, or
12. Any other duplicative federal, state, or local housing subsidy, as determined by HUD. For this purpose, ''housing subsidy'' does not include the housing component of a welfare payment, a Social Security payment received by the family, or a rent reduction because of a tax credit. (June 20, 2019).

Purpose(s): The Computer Matching Agreements describe the respective responsibilities of HUD and the state of Iowa, the state of California, the state of Louisiana, and the CNMI to determine and verify the accuracy of the data, eligibility for their respective benefits, and to preserve the confidentiality of information in accordance with the matching program. The requirements of the Computer Matching Agreements will be carried out by authorized users of the state of Iowa, the state of California, the state of Louisiana, and the CNMI (which include the grantees' authorized employees, and contractors). The agreements also describe the responsibilities of HUD, HUD's CDBG–DR grantees, and DHS–FEMA for other purposes, as described below.

The Computer Matching Agreements establish the terms and conditions governing the CDBG–DR grantees access to, and use of FEMA's Individual Assistance (IA), Individual's and

Household Program data. All FEMA program data that HUD provides to CDBG–DR grantees will be shared via these Computer Matching Agreements between HUD and CDBG–DR grantees that reflect the requirements of the Computer Matching Agreement between FEMA and HUD. The data exchanged between HUD and CDBG–DR grantees will be used to support the duplication of benefits checks conducted by the grantee.

HUD will provide FEMA data to CDBG–DR grantees, pursuant to their separate Computer Matching Agreements, for them to use to determine the correct award amount for eligible program beneficiaries by identifying unmet needs of FEMA applicants; prevent the duplication of benefits; implement the statutory requirement that CDBG–DR funds may not be used for activities reimbursable by or for which funds are made available by FEMA; and implement the statutory requirement to establish procedures to detect and prevent waste, fraud, and abuse of funds.

Categories of Individuals: DHS/FEMA data in this matching program includes individuals that have applied for or expressed interest in disaster assistance. HUD data in this matching program concerns individuals who have applied for or received assistance via HUD assistance programs.

Categories of Records: Data elements disclosed by each agency in this matching program are as follows:

A. From DHS/FEMA to HUD:

- Name (First and Last of Applicant and Co-applicant)
- Date of Birth (Applicant and Co-Applicant)
- Social Security Number (last 4 of Applicant and Co-applicant)
- Phone Number (Applicant Alternate Phone Number, Applicant Current Phone Number, Co-applicant Current Phone Number)
- Email Address of Applicant
- Applicant Registration Number
- Current Mailing Address (Street, City, County, State, Zip Code)
- Current Location (as identified in applicant registration and applicant information screen)
- Damaged Dwelling Latitude and Longitude
- Damaged Address (Street, City, County, State, Zip Code + 4 Digit Ext.)
- Access and Functional Needs (Y/N)
- Household Member Age Range (Under 5 years, 5 to 17 years, 18 to 64 years, 65 and above)
- Number of Household Members
- Number of Dependents in Household
- Current Hotel (Name, Address, City, County)
- Initial Rental Assistance Approved Date
- Direct Housing First Licensed-In Date
- Last Continued Temporary Housing Assistance Date
- Small Business Administration (SBA) HAPP Referral Flag (Y/N)
- Census Block Group ID (if applicable)
- Cause(s) of Damage from Inspection
- Destroyed Flag (Y/N)
- Disaster Number
- Flood Zone
- High Water Mark Location
- High Water Depth in Inches
- Habitability Repairs Required (Y/N)
- Gross Income (as reported at Registration)
- Insurance Types (Insurance Code)
- Level of Damage
- Owner/Renter
- Personal Property Total FEMA Verified Loss (FVL)Amount
- Personal Property Flood Damage FVL Amount
- Real Property Total FVL Amount (Aggregated for all REAL PROPERTY FVL)
- Real Property Flood Damage FVL Amount
- Residence Type
- FEMA Inspection Completed (Y/N)
- Primary Residence (RI) (Yes/No)
- Household Member Age and Name (First and Last)
- Insurance Settlement Flood Amount
- Insurance Settlement Other Amount
- Non-Compliant with Flood Insurance Requirement NCOMP Flag (Y/N)
- Temporary Housing Unit (THU)—Latest Currently Licensed-In Date
- Total Housing Assistance Approved Amount (Aggregated Eligibility Amount)
- Total Housing Assistance Approved Flood Damage Amount
- Total Other Assistance Approved Amount (Aggregated Eligibility Amount)
- Total Other Assistance Flood Damage Approved Amount
- Total Other Needs Assistance Approved Amount (Aggregated Eligibility Amount)
- Total Other Needs Assistance Flood Damage Approved Amount
- Total Personal Property Assistance Approved Amount (Aggregated Eligibility Amount)
- Total Personal Property Assistance Flood Damage Amount
- Total Repair Assistance Approved Amount (Aggregated Eligibility Amount)
- Total Repair Assistance Flood Damage Amount
- Total Replacement Assistance Approved Amount (Aggregated Eligibility Amount)

B. From HUD to HUD Grantee:

- Alternate Current Contact Phone Number
- SBA Referral Flag (Y/N)
- Co-registrant Date of Birth
- Co-registrant First Name
- Co-registrant Last Name
- Co-registrant SSN
- Current Contact Phone Number
- Current Location
- Current Mailing 5 Digit Zip Code
- Current Mailing Address City
- Current Mailing Address Street
- Current Mailing State
- Current Mailing Zip 4 Digit Extension
- Damaged Dwelling Address County
- Damaged Dwelling Latitude
- Damaged Dwelling Longitude
- Damaged Dwelling Address 5 Digit Zip Code
- Damaged Dwelling Address City
- Damaged Dwelling Address Street
- Damaged Dwelling State
- Damaged Dwelling Zip Code 4 Digit Extension
- Dependents (Number in Household)
- Destroyed Flag (Y/N)
- Disaster Number
- FEMA Inspection Completed (Y/N)
- FEMA Registration Number
- Flood Zone
- Gross Income
- High Water Mark Location
- High Water Depth in Inches
- Household Member Age
- Household Member First Name
- Household Member Last Name
- Inspection Completion (Y/N)
- Insurance Settlement Flood Amount
- Insurance Settlement Other Amount
- Insurance Type (Insurance Code)
- NCOMP Flag (Y/N)
- Owner/Renter
- Personal Property Total FVL Amount (Aggregated for all PERSONAL PROPERTY FVL one field replaces all fields related to personal property damage) Personal Property Flood Damage FVL Amount
- Primary Residence (RI) (Yes/No)
- Real Property Total FVL Amount (Aggregated for all REAL PROPERTY FVL (one field replaces all fields related to real property damage) Real Property Flood Damage FVL Amount
- Registrant Date of Birth
- Registrant First Name
- Registrant Last 4 Digits of SSN
- Registrant Last Name
- Residence Type
- Temporary Housing Unit (THU)—Latest Currently Licensed-in Date
- Total Housing Assistance Approved Amount (Aggregated Eligibility Amount)
  Total Housing Assistance Approved Flood Damage Amount
- Total Other Assistance Approved Amount (Aggregated Eligibility Amount)

Total Other Assistance Flood Damage Approved Amount
- Total Other Needs Assistance Approved Amount (Aggregated Eligibility Amount) Total Other Needs Assistance Flood Damage Approved Amount
- Total Personal Property Assistance Amount (Aggregated Eligibility Amount)
  Total Personal Property Assistance Flood Damage Amount
- Total Repair Assistance Approved Amount (Aggregated Eligibility Amount)
  Total Repair Assistance Flood Damage Amount
- Total Replacement Assistance Approved Amount (Aggregated Eligibility Amount)

System(s) of Records:

- DHS/FEMA–008 Disaster Recovery Assistance Files System of Records Notice, 78 FR 25282 (April 30, 2013), or as amended.

Bradley S. Jewitt,

Senior Agency Official for Privacy, Department of Housing & Urban Development.

[FR Doc. 2023–04953 Filed 3–9–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–FR–7076–N–06; OMB Control No. 2577–0294]

60-Day Notice of Proposed Information Collection: Moving to Work Amendment to Consolidated Annual Contributions Contract (ACC)

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* May 9, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Leea Thornton, Office of Policy, Program and Legislative Initiatives, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 3178, Washington, DC 20410; telephone 202–402–6455. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Thornton.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Background

In order to implement the expanded MTW program under division L, title II of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, December 18, 2015), HUD issued the first Operations Notice of the Expansion of the Moving to Work Demonstration Program Solicitation of Comment (82 FR 8056, January 23, 2017) (Operations Notice), and solicited public comment. This notice established requirements for the implementation and continued operation of the expansion of the MTW demonstration program pursuant to the 2016 MTW Expansion Statute and certain pre-approved waivers to establish program flexibility for participants. These waivers will be available to MTW PHAs when the revised MTW ACC Amendment is executed. The Operations Notice also provided that the 100 PHAs would be selected in cohorts, with applications for each cohort to be sought via a Selection Notice.

This initial Operations Notice was followed by subsequent **Federal Register** notices. On May 4, 2017, HUD published the Operations Notice for the Expansion of the Moving to Work Demonstration Program Solicitation of Comment; Waiver Revision and Reopening of Comment Period.'' On October 5, 2018, HUD published a further Operations Notice (83 FR 50387) (a correction and extension of the comment period was published on October 11, 2018 (83 FR 51474)). This notice made changes as a result of the prior public comments, and again solicited public comments. After reviewing these comments and making changes, the Operations Notice was then published for implementation on August 28, 2020 (85 FR 53444).

On December 27, 2018, HUD issued for public comment the 60-day notice for the Moving to Work Amendment to the Consolidated Annual Contributions Contract (the ''MTW ACC Amendment'') under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (83 FR 66738). The MTW ACC Amendment was revised in response to public comments received under the 60-day Notice. The formal title was also changed to the ''Moving to Work Amendment to the Annual Contributions Contract(s).'' On, November 8, 2019, HUD issued for the public comment the 30-day notice for The MTW ACC Amendment. The MTW ACC Amendment was further revised in response to public comments received under the 30-day Notice, and published for use on August 31, 2020. This notice seeks public comment on the renewal of MTW ACC Amendment.

B. Overview of Information Collection

Title of Information Collection: Moving to Work Amendment to Consolidated Annual Contributions Contract(s).

OMB Approval Number: 2577–0294.

Type of Request: Renewal of a currently approved collection.

Form Number: HUD–50166.

Description of the need for the information and proposed use: The proposed Moving to Work (MTW) Amendment to the Annual Contributions Contract(s), signed by HUD and the selected Public Housing Authority (PHA), is necessary for HUD to implement the expansion of the Moving to Work program enacted by Congress in the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, approved December 18, 2015) (2016 Appropriation). It establishes the basic terms and conditions that will apply to 100 new PHAs participating in the MTW demonstration pursuant to the 2016 Appropriation. Specifically, the

MTW ACC Amendment amends any ACCs for the public housing or housing choice voucher programs in effect between the PHA and HUD to establish the PHA's designation as an MTW agency and to operate in accordance with the requirements of the MTW demonstration program, as amended by Public Law 114–113. The MTW ACC Amendment establishes the terms of participation in MTW, including the requirement that the PHA follow the MTW Operations Notice and its respective Selection Notice. The PHAs remain subject to the applicable ACCs to the extent that the provisions thereof are not otherwise waived by the Operations Notice or the applicable MTW Selection Notice. Additionally, the MTW ACC Amendment outlines PHA transition out of the demonstration and HUD termination rights upon PHA default. A copy of the proposed MTW ACC Amendment is published at the end of this notice.

Respondents: Public Housing Authorities.

Estimated Number of Respondents: 100.

Estimated Number of Responses: 100.

Frequency of Response: 1.

Total Estimated Burdens: The burden costs associated with this collection are as follows:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
HUD–50166 MTW ACC Amendment.	100	1 each	0	1.00	0	$52.88	$5,288

The burden costs shown represent burden associated with a one-time review and execution of the MTW ACC Amendment for 100 PHAs to be designated as MTW pursuant to the FY2016 Appropriations Statute.

C. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

D. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Steven Durham,

Acting Chief, Office of Policy, Programs and Legislative Initiatives.

Moving to Work Amendment to Annual Contributions Contract(s)

Section 1. This Moving to Work (MTW) Amendment to the Annual Contributions Contract(s) (MTW ACC Amendment) is entered into between the United States Department of Housing and Urban Development (''HUD'') and _____ (the ''Public Housing Agency, ''PHA'').

Section 2. This MTW ACC Amendment is an amendment to any Annual Contributions Contract(s) (''ACC'') or Annual Contributions Terms and Conditions (''ACC'') in effect between the PHA and HUD for the Public Housing and Housing Choice Voucher programs.

Section 3. The ACC is amended in connection with the PHA's designation as a participant in the expansion of the MTW demonstration pursuant to Section 239 of the Consolidated Appropriations Act, 2016, Public Law 114–113; 129 Stat. 2897 (2016 MTW Expansion Statute) and Section 204 of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1996, Public Law 104–134; 110 Stat. 1321–281 (1996 MTW statute). The PHA's participation in the expansion of the MTW demonstration shall be governed by the MTW Operations Notice for the Expansion of the Moving to Work Demonstration as it is issued as it and may be amended in the future, or any successor notice issued by HUD, (''the MTW Operations Notice'').

Section 4. The term of this amendment shall be for 20 years from the beginning of the PHA's first full fiscal year following execution by the PHA and HUD; or, until termination of this amendment, whichever is sooner.

Section 5. Requirements and Covenants.

(A) As a participant in the MTW demonstration, the PHA must operate in accordance with the express terms and conditions set forth in the MTW Operations Notice. The MTW Operations Notice may be superseded or amended by HUD at any time during the twenty-year MTW term.

(B) The PHA will cooperate fully with HUD and its contractors for the duration of the HUD-sponsored evaluation of the cohort of the MTW Expansion for which the PHA was selected and shall comply with all aspects of its Cohort Study as outlined in the selection notice under which the PHA was designated.

(C) The PHA is only exempted from specific provisions of the Housing Act of 1937 (''the Act'') and its implementing regulations as specified in the MTW Operations Notice. Each such exemption also extends to subregulatory guidance to the extent that the subregulatory guidance implements the provisions of the Act or its implementing regulations exempted pursuant to the MTW Operations Notice. The PHA remains subject to all other applicable requirements including, but not limited to, those in Title 24 of the Code of Federal Regulations and Title 42 of the U.S. Code, Appropriations Acts, Annual Contributions Contracts, notices of funding availability under which the PHA has received funds, and the applicable requirements listed in the MTW Operations Notice (collectively, ''the Requirements''), as they may be amended or implemented in the future. Accordingly, if any Requirement, other than the provisions of the Act and its implementing regulatory requirements or subregulatory guidance exempted pursuant to this MTW ACC Amendment and the MTW Operations Notice, conflicts with any exemption or authorization granted by this MTW ACC Amendment, the MTW Agency remains subject to that Requirement.

Section 6. At least one year prior to expiration of this MTW ACC Amendment,[1] the PHA shall submit a

[1] Should the PHA receive an extension(s) of its MTW participation (*e.g.,* by extension or replacement of its MTW ACC Amendment) the

transition plan to HUD. It is the PHA's responsibility to be able to end all MTW activities that it has implemented through its MTW Supplement to the PHA Plan upon expiration of this MTW ACC Amendment. The transition plan shall describe plans for phasing out such activities. The plan may also include any proposals of authorizations/features of the ACC Amendment and the MTW Operations Notice that the PHA wishes to continue beyond the expiration of the MTW ACC Amendment. The PHA shall specify the proposed duration and shall provide justification for extension of such authorization/features. HUD will review and respond to timely-submitted transition plans from the PHA in writing within 75-days or they are deemed approved. Only authorizations/features specifically approved for extension shall continue beyond the term of the MTW ACC Amendment. The extended features shall remain in effect only for the duration and in the manner specified in the approved transition plan and be subject to any necessary ACC Amendments as required by HUD.

Section 7. Termination and Default.

(A) If the PHA violates or fails to comply with any requirement or provision of the ACC, including this amendment, HUD is authorized to take any corrective or remedial action described in this Section 7 for PHA default or any other right or remedy existing under applicable law, or available at equity. HUD will give the PHA written notice of any default, which shall identify with specificity the measures, which the PHA must take to cure the default and provide a specific time frame for the PHA to cure the default, taking into consideration the nature of the default. The PHA will have the opportunity to cure such default within the specified period after the date of said notice, or to demonstrate within 10 days after the date of said notice, by submitting substantial evidence satisfactory to HUD, that it is not in default. However, in cases involving clear and apparent fraud, serious criminal behavior, or emergency conditions that pose an imminent threat to life, health, or safety, if HUD, in its sole discretion, determines that immediate action is necessary it may institute the remedies under Section 7(B) of this MTW ACC Amendment without giving the PHA the opportunity to cure.

(B) If the PHA is in default of this MTW ACC Amendment and/or the MTW Operations Notice and the default has not been cured, HUD may, undertake any one or all remedies available by law, including but not limited to the following:

i. Require additional reporting by the PHA on the deficient areas and the steps being taken to address the deficiencies;

ii. Require the PHA to prepare and follow a HUD-approved schedule of actions and/or a management plan for properly completing the activities approved under this MTW ACC Amendment;

iii. Suspend the MTW waiver authorization for the affected activities;

iv. Require reimbursement by the PHA to HUD for amounts used in violation of this MTW ACC Amendment;

v. Terminate this MTW ACC Amendment and require the PHA to transition out of MTW;

vi. Restrict a PHA's ability to use its MTW funding flexibly; and/or

vii. Take any other corrective or remedial action legally available.

(C) The PHA may choose to terminate this MTW ACC Amendment at any time. Upon HUD's receipt of written notification from the PHA and a copy of a resolution approving termination from its governing board, termination will be effective. The PHA will then begin to transition out of MTW and will work with HUD to establish an orderly phase-out of MTW activities, consistent with Section 6 of this MTW ACC Amendment.

(D) Nothing contained in this ACC Amendment shall prohibit or limit HUD from the exercise of any other right or remedy existing under any ACC or available under applicable law. HUD's exercise or non-exercise of any right or remedy under this amendment shall not be construed as a waiver of HUD's right to exercise that or any other right or remedy at any time.

Section 8. Notwithstanding any provision set forth in this MTW ACC Amendment, any future law that conflicts with any provision of this ACC Amendment, as determined by HUD, shall not be deemed to be a breach of this ACC Amendment. Nor shall HUD's execution of any future law be deemed a breach of this ACC Amendment. Any future laws affecting the PHA's funding, even if that future law causes a decrease in the PHA's funding, shall not be deemed a breach of this ACC Amendment. No future law or HUD's execution thereof shall serve as a basis for a breach of contract claim in any court.

Section 9. If any clause, or portion of a clause, in this Agreement is considered invalid under the rule of law, it shall be regarded as stricken while the remainder of this Agreement shall continue to be in full effect.

In consideration of the foregoing covenants, the parties do hereby execute this MTW ACC Amendment:

PHA

_____

By: _____

Its: _____

Date: _____

United States Department of Housing and Urban Development

_____

By: _____

Its: _____

Date: _____

[FR Doc. 2023–04954 Filed 3–9–23; 8:45 am]

BILLING CODE 4210–67–P

transition plan will be due one year prior to the end of the extension(s).

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7075–N–01]

60-Day Notice of Proposed Information Collection: Study of Childcare in Public Housing; OMB Control No.: 2528–XXX

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* May 9, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC

20410–5000; telephone 202–402–5535 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna Guido at *Anna.Guido@hud.gov,* telephone 202–402–5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Study of Childcare in Public Housing Data Collection.

OMB Approval Number: 2528–New.

Type of Request (*i.e.,* new, revision or extension of currently approved collection): New Collection.

Form Number: N/A.

Description of the need for the information and proposed use: The purpose of this proposed information collection is to interview key stakeholders and HUD assisted families to support the Study of Childcare in Public Housing. This is a multi-site study including six Public Housing Authorities (PHAs) in three states.

Individual interviews will be conducted with key stakeholders and PHA residents in each of the six sites.[1] These interviews are key to our understanding of the Early Care and Education (ECE) needs, preferences, and use of families in PHA-owned housing. Furthermore, these interviews will help us better understand the barriers and facilitators to operating co-located PHA and ECE programs.

Stakeholder interviews: Within each site, a key set of stakeholders will be identified through the landscape scan. Key stakeholders will include those involved in the operations of either a PHA, an ECE program, or a co-located ECE program in PHA housing in a given community. Within each site, we anticipate conducting up to 16 stakeholder interviews with a mix of virtual or in-person interviews, depending on the preferences of the stakeholders and local public health guidelines.[2] Potential stakeholders may include: PHA directors, PHA resident advisory board members, PHA supportive service staff, Head Start grantee directors, Pre-K directors, child care resource and referral centers, state child care subsidy office directors, and state Head Start Collaboration Office directors.

We anticipate conducting semi-structured interviews with key stakeholders. Interview questions will address, but not be limited to, the following topics: (1) Whether there is a co-located ECE; (2) If there is a co-located ECE, processes for licensure and quality rating assessments (if applicable); (3) Facilitators and challenges with operating co-located ECE (as applicable); (4) How local ECE policies effect the colocation of ECE and PHAs; (5) How PHAs support families in accessing ECE; (6) Proximity of ECE programs to PHA (*e.g.,* whether the program is in a child care desert or location with many options available); and (7) Characteristics of local ECE programs (*e.g.,* cost, capacity, licensure status, ages served, home- or center-based, and hours of operation).

PHA resident interviews: In-depth interviews are critical to understanding sensitive topics that people might be reluctant to discuss in a group. Given our previous experience with qualitative data collection in various housing programs and contexts, we anticipate that individual interviews will allow us to better understand the specific needs and experiences of families. We plan to work closely with resident advisory boards and key stakeholders in each site to identify the best process for recruiting families to participate in the study. Recruitment strategies will be responsive to local contexts and sensitive to families' preferences. We anticipate recruiting families with diverse needs and experiences, including variation in child age, employment status, and childcare arrangements. We will work with the resident advisory board, as applicable, to vet interview questions prior to data collection.

We anticipate conducting semi-structured interviews with residents. Interview questions will address, but not be limited to, the following topics: (1) ECE needs, preferences, and use; (2) What families look for in terms of the quality of care; (3) Facilitators and barriers to accessing ECE (*e.g.,* cost, location, etc.), (4) Interest and use of co-located ECE programs; and (5) Support received from PHAs in accessing ECE.

This **Federal Register** Notice provides an opportunity to comment on the data collection instruments and associated materials to be administered to the participants in the Study of Childcare in Public Housing.

Hourly Cost per Response: Key stakeholders include: PHA directors, PHA resident advisory board members, PHA supportive service staff, Head Start grantee directors, Pre-K directors, childcare resource and referral centers, state child care subsidy office directors, and state Head Start Collaboration Office directors. Mean Hourly Wage rates are estimated using approximations from the U.S. Bureau of Labor Statistics (BLS):[3]

- Education/Child Care Administrators—$47.73
- Education/Child Care Administrators (Pre School)—$25.87
- Child, Family, School Social Workers—$26.39
- Mean = (47.73 + 25.87 + 26.39)/3 = $33.33
- Loaded Mean (+30%) = $43.33

Respondents (i.e., affected public): Public Housing residents and key stakeholders who may include: PHA directors, PHA resident advisory board members, PHA supportive service staff, Head Start grantee directors, Pre-K directors, child care resource and referral centers, state child care subsidy office directors, and state Head Start Collaboration Office directors. All respondents shall be adults.

Estimated Number of Respondents: 96 key stakeholder respondents (16 per PHA * 6 PHAs) and 108 PHA resident respondents (18 per PHA * 6 PHAs).

Frequency of Response: Once.

Average Hours per Response: Completion the 96 Key Stakeholder Interviews is expected to take on average 50 minutes or 0.83 hours, with the consent form taking an additional 10 minutes or .17 hours per respondent. Completion of the 108 PHA Resident Interviews is expected to take on average 50 minutes or 0.83 hours, with

[1] Interviews with state-level stakeholders will primarily be conducted virtually. Interviews with site-level stakeholders and families will primarily be held in person, depending on public health guidelines at the time of data collection.

[2] We anticipate one to two interviews per stakeholder group.

[3] BLS table with wages: *https://www.bls.gov/oes/current/oes_nat.htm#top.*

the consent form taking an additional 10 minutes or .17 hours per respondent.

Total Estimated Burden Hours: 204 hours.

ANNUALIZED BURDEN TABLE

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
Adult Head of Household							
Key Stakeholders Interviews	96	1	1	0.83	80	$43.33	$3,466.40
Key Stakeholders Consent Form	96	1	1	.17	16	43.33	693.28
PHA Residents Interviews	108	1	1	0.83	90	10.62	955.80
PHA Resident Consent Form	108	1	1	.17	18	10.62	191.16
Total					204		5,306.64

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2023–04950 Filed 3–9–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–NCTC–2023–0007; FXGO16610900600–234–FF09X35000; OMB Control Number 1018–0176]

Agency Information Collection Activities; Native Youth Climate Adaptation Leadership Congress

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before May 9, 2023.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference 1018–0176 in the subject line of your comments):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–NCTC–2023–0007.
- *Email: Info_Coll@fws.gov.*
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Service offers eligible Native American, Alaskan Native, and Pacific Islander high school students the opportunity to apply for the Native Youth Climate Adaptation Leadership Congress (Congress). The mission of the Congress is to develop future conservation leaders with the skills, knowledge, and tools to address environmental change and conservation challenges to better serve their schools and home communities. The Congress supports and operates under the following authorities:

- Executive Order (E.O.) 13175, ''Consultation and Coordination With Indian Tribal Governments'' (November 6, 2000);
- E.O. 13515, ''Increasing Participation of Asian Americans and Pacific Islanders in Federal Programs'' (October 14, 2009);
- E.O. 13592, ''Improving American Indian and Alaska Native Educational Opportunities and Strengthening Tribal Colleges and Universities'' (December 2, 2011);
- Public Law 116–9, Section 9003, ''John D. Dingell, Jr. Conservation, Management, and Recreation Act'' (March 12, 2019);
- 16 U.S.C. 1727b, Indian Youth Service Corps;
- White House Memorandum on Government-to-Government Relationships with Tribal Governments (September 23, 2004);
- Secretary's Order (S.O.) 3206, ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act,'' issued jointly by the Department of the Interior and the Department of Commerce (June 5, 1997);
- S.O. 3317, ''Department of the Interior Policy on Consultation with Indian Tribes'' (December 1, 2011);
- S.O. 3335, ''Reaffirmation of the Federal Trust Responsibility to Federally Recognized Indian Tribes and Individual Indian Beneficiaries'' (August 20, 2014); and
- The Service's Native American Policy (510 FW 1), published January 20, 2016.

The following Federal partners assist and support the Service's administration of the Congress:

- The U.S. Department of the Interior—
  - —Bureau of Indian Affairs;
  - —Bureau of Land Management;
  - —National Park Service; and
  - —United States Geological Survey;
- The U.S. Department of Agriculture—U.S. Forest Service;
- The U.S. Department of Commerce—National Oceanic and Atmospheric Administration;
- The Federal Emergency Management Agency;
- The National Aeronautics and Space Administration; and
- The Environmental Protection Agency.

The weeklong environmental Congress fosters an inclusive and meaningful educational opportunity for aspiring Indigenous youth leaders interested in addressing environmental issues facing Native American, Alaskan Native, and Pacific Islander communities. Eligible students—representing a diverse mix of Indigenous communities from various geographic locations, both urban and rural—compete for the opportunity to represent their communities from across the country. The students learn about environmental change and conservation while strengthening their leadership skills for addressing conservation issues within their own communities.

Through a cooperative agreement with the New Mexico Wildlife Federation (NMWF), the Service solicits and evaluates applications from eligible students interested in applying for the program. The NMWF notifies successful applicants and arranges all travel for them. Information collected from each applicant via an online application administered by the NMWF includes:

- Applicant's full name, contact information, date of birth, and Tribal/community affiliation;
- Emergency contact information for applicant;
- Name and contact information of applicant's mentor;
- Applicant's school name and address;
- Applicant's current grade in school;
- Applicant's participation in extracurricular activities, school clubs, or community organizations;
- Applicant's volunteer experience; and
- Applicant's accomplishments or awards received.

Each applicant provides essay responses to questions concerning topics such as environmental issues affecting their home/Tribal community, how or whether the environmental issues are addressed, and/or how, as a Native youth leader, they can lead the community in adapting to a changing environment.

In addition to the online application form, the Service uses following forms in conjunction with the Congress:

- Form 3–2525, ''Native Youth Climate Adaptation Leadership Congress Student Medical Information''—collects the following information:
  - —Student's full name and preferred name;
  - —Date of birth;
  - —Age;
  - —Health insurance policy information;
  - —Medication information, to include dose and frequency;
  - —Drug and/or food sensitivities/allergies;
  - —Medications and immunizations; and
  - —Pre-existing condition(s).
- Form 3–2546, ''Enrollment Form''—collects the following information:
  - —Applicant's full name, address, and contact information;
  - —Parent/guardian name and contact information;
  - —Student's age, date of birth, and gender;
  - —Student's high school year;
  - —Student's high school name, address, and contact information; and
  - —Chaperone name.
- Form 3–2547, ''Parental Consent Form''—collects the following information:
  - —Name of student and date of birth;
  - —Student address, school, grade, and contact information; and
  - —Student's physician name, address, and contact information.
- Form 3–2548, ''Student Conduct Agreement''—collects the following information:
  - —Student's full name and preferred name;
  - —Student signature and signature date; and
  - —Parent/guardian name, signature, and signature date.
- Form 3–2549, ''Mentor Waiver''—collects the following information:

—Mentor name;
—Mentor signature and signature date;
—Emergency contact name and contact number.

We require successful students to provide basic medical information so that we can assure their health and safety while on site at the National Conservation Training Center. The on-site nurse keeps this information strictly confidential, for use only in an emergency.

Proposed Revisions

With this submission, the Service proposes to revise Form 3–2546 to expand options for providing gender identity. We also updated the title of the collection to be Native Youth Climate Adaptation Leadership Congress (from Native Youth Community Adaptation and Leadership Congress). Finally, we will also seek OMB approval of an additional Form 3–2950 which collects travel and personal identification information for students attending the Congress. This new form will collect the following information:

• Name, contact information, date of birth, and group/school/community name for chaperone;
• Identifying information for groups participants, to include name, date of birth, phone number, and gender (required by airline);
• Airport information;
• Special travel needs;
• Address for travel stipend payments; and
• Additional comments or questions.

The public may request copies of any form contained in this information collection by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**).

Title of Collection: Native Youth Climate Adaptation Leadership Congress.

OMB Control Number: 1018–0176.

Form Numbers: Forms 3–2525, 3–2546, 3–2547, 3–2548, 3–2549, and 3–2950.

Type of Review: Revision of a currently approved information collection.

Respondents/Affected Public: Eligible high school or college students interested in applying for the program.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity	Total annual responses	Completion time per response	Total annual burden hours
Application (online)	105	4 Hours	420
Form 3–2525, Student Medical Information	100	30 Mins	50
Form 3–2546, Enrollment Form	100	18 mins	30
Form 3–2547, Parental Consent Form	100	12 Mins	20
Form 3–2548, Student Conduct Agreement	100	12 Mins	20
Form 3–2549, Mentor Waiver	30	12 Mins	6
Form 3–2950, Travel Form	100	20 Mins	33
Totals	635		579

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2023–04911 Filed 3–9–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2023–N017; FXMB12310900WH0–234–FF09M26000; OMB Control Number 1018–0023]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Migratory Bird Surveys

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments on or before April 10, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference ''1018–0023'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations in the Code of Federal Regulations (CFR) at 5 CFR 1320, all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

On June 22, 2022, we published in the **Federal Register** (87 FR 37353) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on August 22, 2022. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests, the

Service also published the **Federal Register** notice on *Regulations.gov* (Docket FWS–HQ–MB–2022–0077) to provide the public with an additional method to submit comments (in addition to the typical *Info_Coll@fws.gov* email and U.S. mail submission methods). We received the following comments in response to that notice:

Comment 1: From Wyoming Game and Fish Department (Angi Bruce, Deputy Director), received 8/9/2022 by email:

The Wyoming Game and Fish Department (Department) provided the following comment in response to our first question in the **Federal Register** notice (''Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility''):

The data provided from these surveys is utilized by Department biologists and is crucial for the management of migratory game bird populations in the State of Wyoming and across State boundaries. Without this data, it would be difficult for our biologists to set harvest limits and determine proper season dates.

(2) The Department provided the following comment in response to question 2 in the **Federal Register** notice (''The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used''):

The Department has not conducted an in-depth review of the methodology and assumptions used to determine the ''burden'' associated with these surveys. However, given that this data has been used historically to successfully manage migratory game birds across State boundaries, the Department appreciates the USFWS efforts and recommends continuing these data collection efforts.

(3) The Department provided the following comment in response to question 3 in the **Federal Register** notice (''Ways to enhance the quality, utility, and clarity of the information to be collected''):

The Department appreciates the USFWS's past efforts to modernize the surveys through consultation with various partners and utilizing new technologies. The Department encourages the USFWS to continue utilizing emerging technologies to further enhance the quality, utility, and clarity of the surveys. The Department supports the USFWS efforts to compare old and new data collection methodologies to ensure data integrity and comparability of data sets.

(4) The Department provided the following comment in response to question 4 in the **Federal Register** notice (''How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response''):

As previously mentioned, the Department appreciates the USFWS's efforts to modernize data collection procedures and utilize emerging technologies. The Department recommends that the USFWS continue to utilize automated electronic messaging approaches to send surveys to hunters and also remind them to submit this vital data. The Department also recommends that the USFWS provide technical assistance to respondents as necessary to accommodate for some users' lack of access to, or difficulty using, new technology.

Agency Response to Comment 1, from the Wyoming Game and Fish Department: We have utilized, and are continuing to explore, new technologies to increase efficiencies, reduce costs, and improve data quality in both the online harvest survey and Parts Collection Survey. For example, we are conducting a pilot project to evaluate the efficacy of bird photos submitted by hunters to supplement the Parts Collection Survey, and will be developing a prototype mobile phone app for taking and submitting photos. We have collaborated with State partners and the Association of Fish and Wildlife Agencies to promote the Harvest Information Program with targeted outreach efforts and materials. We have expanded communication options for hunters to contact us for technical support, including an additional email address and contact form that are monitored by technical support providers, and we have developed a clerical interface with the online survey database so that clerks can access information to assist hunters with technical support. Also, we have collected data from a side-by-side 3-year comparison of both the online and paper surveys and are analyzing those data to evaluate any possible differences in harvest estimates arising from use of the two platforms. This information will be provided to States and other partners when completed, to allow a better understanding of the effects of changing data collection platforms on the time series of migratory bird harvest provided by the Migratory Bird Harvest Survey.

Comment 2: From Andrew Reamer, submitted 6/22/22 by email:

On behalf of the American Economic Association and the Industry Studies Association, I write to request a copy of the draft ICR for the Migratory Bird Information Program and Migratory Bird Surveys—1018–0023, as invited by today's **Federal Register**. Thank you and we look forward to seeing the materials when they are available. Please feel free to upload them to *https://www.regulations.gov/docket/FWS-HQ-MB-2022-0077.*

Agency Response to Comment 2: We provided a draft ICR as requested.

Comment 3: Email comment from Jean Publieeer, submitted on 06/22/2022—The commenter did not address the information collection requirements.

Agency Response to Comment 3: No response required.

Comment 4: Anonymous comment, submitted on 08/15/2022—The commenter did not address the information collection requirements.

Agency Response to Comment 4: No response required.

Comment 5: From Atlantic Flyway Council (Gray Anderson), submitted 8/21/22 by email:

The Atlantic Flyway Council (AFC) provided the following comment in response to our question 1 in the **Federal Register** notice (''Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility''):

The data obtained from these surveys are crucial for the proper management of migratory game bird populations, and for the provision of hunting opportunity. The Flyway Councils and USFWS maintain a longstanding cooperative partnership to set (and when necessary, adjust) hunting regulations based on the best available scientific information. Without the data on hunter activity and harvest obtained from these surveys, management decisions would be more likely to result in migratory bird populations being higher or lower than desired, and/or could unnecessarily restrict recreational opportunities. Further, the long time series and statistical reliability of the harvest surveys data places migratory game bird hunting on a solid footing against any legal challenges. For these reasons, the AFC firmly believes that continuing to collect the data provided by these surveys is necessary and provides practical utility not only for the USFWS, but also for the AFC's member agencies.

AFC provided the following comment in response to our question 2 in the **Federal Register** notice (''The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used''):

The methodology and assumptions used to estimate the time burden for this collection of information are not clear to the AFC. However, from our involvement in various aspects of the surveys, the estimates appear reasonably accurate. We do not believe the surveys place a significant burden on respondents, and in any case the benefits provided to wildlife managers and resource users from having this information make it well worth the investment of time and effort needed to collect it.

AFC provided the following comment in response to our question 3 in the **Federal Register** notice (''Ways to enhance the quality, utility, and clarity of the information to be collected''):

The AFC is pleased to note that, in keeping with its comments provided in 2017 on a previous iteration of this information collection request, the USFWS has made significant strides in improving and modernizing its migratory bird harvest surveys over the past 5 years. The transition to an online survey platform appears to be progressing well and has improved data quality and reduced costs, without increasing the burden for respondents. The USFWS has also performed and partnered in various biological, social science, and statistical work to ensure that sample frames and survey question structure are maximizing survey efficiency and data quality, and that wings and tails in the Parts Collection Survey are appropriately classified. We encourage the USFWS to proceed with the side-by-side comparison of old and new survey methodology described in the **Federal Register** notice and we reiterate our commitment to assist the USFWS with identifying and implementing further improvements that will enable the harvest surveys to keep pace with and take advantage of technological advances.

It should also be noted that an important element in data quality and cost control is ensuring the sample frames include all relevant migratory game bird hunters—but only migratory game bird hunters—and that surveyed hunters understand the vital importance of their participation. In this regard, the Association of Fish and Wildlife Agencies' Harvest Information Program Communication Plan is a valuable resource and we encourage the USFWS to incorporate appropriate elements of that plan in its communications with the hunting public.

AFC provided the following comment in response to our question 4 in the **Federal Register** notice (''How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response''):

As noted above, the USFWS has made good use of appropriate technologies in recent years to enhance data quality, reduce costs, and minimize burden on respondents. As information technology continues to rapidly advance, currently unforeseen methodologies are likely to arise and the entire migratory game bird management community should remain attuned to these opportunities.

Finally, it is important to highlight the AFC's increasing concern regarding inadequate Federal agency funding for many aspects of migratory bird management, including the harvest surveys program. It is our understanding that one of the reminders for participants to complete the Migratory Bird Hunter Survey has already been cut due to budget constraints, and that additional cuts to sample frames may need to be considered. These changes negatively affect the accuracy and precision of harvest estimates, and further erosion of data quality could increase the risk of negative conservation outcomes. Consequently, along with requesting that the continuation of these surveys be approved from an administrative standpoint, we urge that the necessary financial resources be provided for ongoing implementation.

The AFC greatly values our partnership with the USFWS in monitoring and managing the migratory bird resources so important to our constituents. We appreciate the opportunity to provide comments on this specific aspect of that partnership and we look forward to working with the USFWS to continue to collect and apply harvest surveys data, and to implement further survey improvements if and when necessary.

Agency Response to Comment 5, from AFC: We have collected data from a side-by-side 3-year comparison of both the online and paper surveys and are analyzing those data to evaluate any possible differences in harvest estimates arising from use of the two platforms. This information will be provided to States and other partners when completed, to allow a better understanding of the effects of changing data collection platforms on the time series of migratory bird harvest provided by the Migratory Bird Harvest Survey. We are working with the Association of Fish and Wildlife Agencies to adopt the Harvest Information Program Communications Plan, and are developing data visualizations and hunter-focused web pages to help hunters and the public understand how we collect harvest data and how we use it in science based harvest and population management.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Migratory Bird Treaty Act (16 U.S.C. 703–711) and the Fish

and Wildlife Act of 1956 (16 U.S.C. 742d) designate the Department of the Interior as the key agency responsible for (1) the wise management of migratory bird populations frequenting the United States, and (2) the setting of hunting regulations that allow appropriate harvests that are within the guidelines that will allow for those populations' well-being. These responsibilities dictate that we gather accurate data on various characteristics of migratory bird harvest. Based on information from harvest surveys, we can adjust hunting regulations as needed to optimize harvests at levels that provide a maximum of hunting recreation while keeping populations at desired levels.

Under 50 CFR 20.20, migratory bird hunters must register for the Migratory Bird Harvest Information Program (HIP) in each State in which they hunt each year. State natural resource agencies must send names and addresses of all migratory bird hunters to the Branch of Monitoring and Information Management, U.S. Fish and Wildlife Service Division of Migratory Bird Management, on an annual basis.

The Migratory Bird Hunter Survey is based on the Migratory Bird Harvest Information Program. We randomly select migratory bird hunters and ask them to report their harvests. The resulting estimates of harvest per hunter are combined with the complete list of migratory bird hunters to provide estimates of the total harvest for the species surveyed.

The Parts Collection Survey estimates the species, sex, and age composition of the harvest, and the geographic and temporal distribution of the harvest. Randomly selected successful hunters who responded to the Migratory Bird Hunter Survey the previous year, as well as a sample of hunters who were not surveyed the previous year, are asked to complete and return a letter if they are willing to participate in the Parts Collection Survey. We provide postage-paid envelopes to respondents before the hunting season and ask them to send in a wing or the tail feathers from each duck or goose that they harvest, or a wing from each mourning dove, woodcock, band-tailed pigeon, or rail that they harvest. We use the wings and tail feathers to identify the species, sex, and age of the harvested sample. We also ask respondents to report the date and location of harvest for each bird on the outside of the envelope. We combine the results of this survey with the harvest estimates obtained from the Migratory Bird Hunter Survey to provide species-specific national harvest estimates.

The combined results of these surveys enable us to evaluate the effects of season length, season dates, and bag limits on the harvest of each species, and thus help us determine appropriate hunting regulations.

The Sandhill Crane Harvest Survey is an annual questionnaire survey of people who obtained a sandhill crane hunting permit. At the end of the hunting season, we randomly select a sample of permit holders and ask them to report the date, location, and number of birds harvested for each of their sandhill crane hunts. Their responses provide estimates of the temporal and geographic distribution of the harvest as well as the average harvest per hunter, which, combined with the total number of permits issued, enables us to estimate the total harvest of sandhill cranes. Based on information from this survey, we adjust hunting regulations as needed.

In fall of 2019, we implemented a new, online platform for the Migratory Bird Hunter Survey. The platform is optimized for use on multiple devices (computer, tablet, or phone, Android or Apple OS). This online survey platform walks a participant through the process of entering their harvest for a single day and asks for one piece of information at a time, which reduces confusion and the likelihood that the hunter will provide incorrect information. The online system improves data quality and prevents errors (*e.g.,* reporting harvest of the wrong species, or in the wrong State). We will continue to conduct the full paper survey through 2022, in order to ensure that data collected through the online platform is sound, and to provide a side-by-side comparison of harvest estimates that can be used to calibrate the old survey to the new one. This is particularly important for maintaining a continuous time series of harvest estimates, despite changing methodology. Going forward, we will conduct the full survey using the online application but will provide a paper survey by mail to those hunters who request them.

Title of Collection: Migratory Bird Information Program and Migratory Bird Surveys, 50 CFR 20.20.

OMB Control Number: 1018–0023.

Form Number: FWS Forms 3–165, 3–165A through E, and 3–2056J through N.

Type of Review: Renewal without change of a currently approved collection.

Respondents/Affected Public: States and migratory game bird hunters.

Respondent's Obligation: Mandatory for HIP registration information; voluntary for participation in the surveys.

Frequency of Collection: Annually for States or on occasion for migratory bird hunters.

Total Estimated Annual Nonhour Burden Cost: None.

Collection type/form No.	Number of respondents	Average number of responses each	Number of annual responses *	Average time per response	Total annual burden hours *
Migratory Bird Harvest Information Program (State Governments)					
	49	18	882	129 hours	113,778
Migratory Bird Hunter Survey (Individuals)					
Form 3–2056J	31,900	1	31,900	4 minutes	2,127
Form 3–2056K	16,900	1	16,900	3 minutes	845
Form 3–2056L	8,500	1	8,500	3 minutes	425
Form 3–2056M	10,200	1	10,200	2 minutes	340
Subtotals	67,500	.....	67,500	.....	3,737
Parts Collection Survey (Individuals)					
Form 3–165	4,760	22	104,720	5 minutes	8,727
Form 3–165A	830	5.5	4,565	5 minutes	380
Form 3–165B	3,600	1	3,600	1 minute	60

Collection type/form No.	Number of respondents	Average number of responses each	Number of annual responses *	Average time per response	Total annual burden hours *
Form 3–165C	320	1	320	1 minute	5
Form 3–165D	800	1	800	1 minute	13
Form 3–165E	780	1.5	1,170	5 minutes	98
Subtotals	11,090		115,175		9,283
Sandhill Crane Harvest Survey (Individuals)					
Form 3–2056N	5,900	1	5,900	1.5 minutes	148
Totals	84,539		189,457		126,946

* Rounded.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2023–04908 Filed 3–9–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500169761; F–020174, F–35871, F–35872]

Notice of Application for Withdrawal Extension; and Public Meeting; Fort Wainwright, AK

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of withdrawal application.

SUMMARY: The Department of the Army (Army) has filed an application with the Bureau of Land Management (BLM) for the extension of the current withdrawal in the Fairbanks North Star Borough and the Southeast Fairbanks Census Area, Alaska. The Army requested an extension of the existing approximately 869,862-acre withdrawal for the Yukon Training Area (formerly Fort Wainwright Yukon Training Range) and the Donnelly Training Areas East and West (formerly Fort Greely East and West Training Ranges) from all forms of appropriation under the public land laws, including the mining laws and the mineral leasing and geothermal leasing laws, for 25 years or more, subject to valid existing rights. The existing withdrawal will expire on November 6, 2026. The decision about this application will be made by Congress. This notice advises the public of an opportunity to comment on this application for a withdrawal extension and to attend a public meeting.

DATES: Comments regarding this withdrawal application must be received by June 8, 2023. In addition, the BLM and Army will host public meetings addressing the withdrawal application. The date, time, and location information for the public meetings are listed in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Comments pertaining to this application for withdrawal extension should be sent to the Alaska State Director, BLM Alaska State Office, 222 West Seventh Avenue, No. 13, Anchorage, Alaska 99513–7504 or by email at *blm_ak_state_director@blm.gov*.

FOR FURTHER INFORMATION CONTACT: Chelsea Kreiner, BLM Alaska State Office, (907) 271–4205, email *ckreiner@blm.gov,* or you may contact the BLM office at the address above. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or Tele Braille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Military Lands Withdrawal Act (MLWA) of 1999 (Pub. L. 106–65) withdrew approximately 869,862 acres of public land comprising Yukon Training Area, Donnelly Training Area East, and Donnelly Training Area West from all forms of appropriation under public land laws and reserved them for use by the Army. The withdrawal will expire on November 6, 2026, unless extended by Congress. The Army has filed an application for extension of the current withdrawal of approximately 869,862 acres of public lands from all forms of appropriation under the public land laws, including the mining laws and the mineral leasing and geothermal leasing laws, for 25 years or more. The purpose of the withdrawal extension is to allow for continued military use of the Yukon Training Area and the Donnelly Training Areas East and West in anticipation of continuing national defense requirements.

The Yukon Training Area covers approximately 246,277 acres and is located approximately 16 miles east-southeast of Fairbanks and immediately east of Eielson Air Force Base. Donnelly Training Areas East and West are located near Fort Greely in the Tanana River valley in central Alaska approximately 80 miles southeast from Fort Wainwright, near the city of Delta Junction in the Southeast Fairbanks Census Area. Donnelly Training Area East is approximately 51,590 acres and Donnelly Training Area West is approximately 571,995 acres. The August 10, 2000, **Federal Register** publication (65 FR 49012) described the approximately 869,862 acres of public lands withdrawn by the MLWA.

The Engle Act (Pub. L. 85–337, 43 United States Code 155–157) requires land withdrawals for defense purposes of more than 5,000 acres in the aggregate for any one defense project or facility to be authorized by Congress through legislation. The MLWA requires the Army to notify the Secretary of the Interior and Congress whether there is a continuing military need for the withdrawn land. The Army and the Department of the Interior (DOI) intend to submit a legislative proposal for extension of the withdrawal and reservation to Congress not later than May 1, 2025.

As required by section 204(b)(1) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(b)(1), and the BLM regulations at 43 CFR part 2300, the BLM is publishing the notice of the Army's application. While the BLM and the DOI assist the Army with

the processing of withdrawal applications, and the Secretary of the Interior makes a recommendation to Congress on applications for withdrawals of this size for defense purposes, Congress will decide whether to extend the existing withdrawal for the Yukon Training Area and Donnelly Training Areas East and West. This notice invites the public to comment on the application for withdrawal extension and notifies the public that a public meeting will occur.

The Army is preparing a legislative environmental impact statement (EIS) in support of the legislative proposal and published a notice of intent to conduct public scoping under the National Environmental Policy Act (NEPA) in the **Federal Register** on September 24, 2021 (86 FR 53038). The Army conducted a virtual public scoping meeting on October 13, 2021, and accepted comments on potential alternatives, potential environmental impacts, information, and analyses relevant to the proposed action. The NEPA scoping period ended on October 25, 2021. The BLM is participating as a cooperating agency in the preparation of the legislative EIS, and the draft legislative EIS is anticipated to be published soon. Information on the environmental review process can be viewed at the Army's project website at *https://www.aklweleis.com/*.

For a period until June 8, 2023, all persons who wish to submit comments in connection with the withdrawal application may present their comments in writing to the Alaska State Director at the address listed in the **ADDRESSES** section earlier. All comments received will be considered before the Secretary of the Interior makes any recommendation for withdrawal to Congress.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

In addition, BLM and Army will host public meetings on Monday, April 10, 2023, at 5:00 p.m. at the Westmark Fairbanks Hotel and Conference Center, Yukon Room, 813 Noble Street, Fairbanks, Alaska, and on Tuesday, April 11, 2023, at 5:00 p.m. at the Delta Junction Community Center, 2287 Deborah Street, Delta Junction, Alaska.

The withdrawal extension application will be processed in accordance with MLWA, and to the extent consistent with MWLA, the regulations set forth in 43 CFR 2310.4 and subject to section 810 of the Alaska National Interest Lands Conservation Act, (16 U.S.C. 3120).

(Authority: 43 CFR 2310.4.)

Steven M. Cohn,

Alaska State Director.

[FR Doc. 2023–04988 Filed 3–9–23; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035446; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California San Diego, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California San Diego has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from San Diego County, CA.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 10, 2023.

ADDRESSES: Eva Trujillo, University of California San Diego, 9500 Gilman Drive, La Jolla, CA 92093, telephone (858) 414–4609, email *e7trujillo@ucsd.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California San Diego. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the University of California San Diego.

Description

Human remains representing, at minimum, one individual were removed from a location near Oceanside, located on the north side of the Loma Alta Valley, in San Diego County, CA. This location is identified as Hubbs site number ''1963:III:31(A).'' In 1963, Dr. Carl Leavitt Hubbs, an employee of the University of California, San Diego/Scripps Institution of Oceanography, removed the human remains and associated funerary objects from the site and incorporated them into what became known as the ''Hubbs Collection.'' The eight associated funerary objects are one lot of charcoal, one lot of chipped stone cores, one lot of chipped stone scrapers, one lot of river rock, one lot of organic residue, one lot of unmodified shell, one lot of unworked flakes, and one lot of utilized flakes.

Dr. Hubbs bequeathed the Hubbs Collection to the Museum of Us (formerly the San Diego Museum of Man) in 1973. In March of 2004, the Museum of Us (MoU) deaccessioned the Hubbs Collection and donated it to the University of San Diego (USD) Anthropology Department, although some of the collection remained at MoU. In June of 2020, the University of California, San Diego (UCSD) became aware of the Hubbs Collection and, in December of 2020, given the scope of the collection and complexities related to provenance, UCSD, MoU, and USD reached an agreement to work together to facilitate NAGPRA compliance.

Cultural Affiliation

The human remains and associated funerary objects described in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: oral tradition, archeological information, and geographical information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the University of California San Diego, CA, has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.

• The eight objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (*previously* listed as Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Jolla Band of Luiseno Indians, California (*previously* listed as La Jolla Band of Luiseno Mission Indians of the La Jolla Reservation); La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Pala Band of Mission Indians (*previously* listed as Pala Band of Luiseno Mission Indians of the Pala Reservation, California); Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Indians (*previously* listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California); Rincon Band of Luiseno Mission Indians of Rincon Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; Soboba Band of Luiseno Indians, California; and the Sycuan Band of the Kumeyaay Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the University of California San Diego must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of California San Diego is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04897 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035451; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Museum of Fine Arts, Boston, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Museum of Fine Arts, Boston (MFA) intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from a site between Matamoras and Dingman's Ferry in Pike County, Pennsylvania.

DATES: Repatriation of the cultural items in this notice may occur on or after April 10, 2023.

ADDRESSES: Julia McCarthy, Interim Director of Collections, Museum of Fine Arts Boston, 465 Huntington Avenue, Boston, MA 02115, telephone (617) 369–3499, email *jmccarthy@mfa.org*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the MFA. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the MFA.

Description

The 11 cultural items were removed in 1962 from the property of Marie Zimmermann, located between Matamoras and Dingman's Ferry, in Pike County, Pennsylvania. The site was excavated by Lenape Chapter 12 of the Society for Pennsylvania Archaeology. During these excavations, 22 Native American graves were uncovered. The objects listed in this notice were kept by an amateur archeologist working at the site. His widow sold them to a New Jersey dealer who, in turn, sold them to the MFA in 1993.

The 11 unassociated funerary objects are seven earthenware vessels (MFA accession nos. 1993.611–1993.616 and 1993.621), two earthenware pipes (1993.617–1993.618), one stone bowl (1993.619), and one stone plumb bob (1993.620). They have been dated to about A.D. 1340 based on their appearance.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, geographical, and historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the MFA has determined that:

• The 11 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.

• There is a relationship of shared group identity that can be reasonably traced between the cultural items and

the Delaware Nation, Oklahoma; Delaware Tribe of Indians; and the Stockbridge Munsee Community, Wisconsin.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the MFA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The MFA is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04901 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–IRMD–NISC–NPS0034680; PPWOCOMM00; PPMPSPD1Y.YM0000; OMB Control Number 1024–NEW]

Agency Information Collection Activities; National Park Service Virtual Visitor Study

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 we, the National Park Service (NPS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before May 9, 2023.

ADDRESSES: Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive (MS–242) Reston, Virginia 20192 (mail); or to *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number 1024–NEW (Virtual Visitor) in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Todd Edgar, Solutions Architect, NPS Information Resources Management Directorate to *todd_edgar@nps.gov* (email) or by telephone at 202–306–3909. Please reference OMB Control Number 1024–NEW (Virtual Visitor) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Under the authority of the Organic Act of 1916, the National Park Service (NPS) is responsible for protecting resources and providing for the enjoyment of current and future generations. Of increasing importance to the NPS, is the experience of virtual visitors to NPS virtual resources. The NPS Virtual Visitor Study is a new information collection request. The study will administer online surveys to users who visit NPS digital assets, including *NPS.gov,* park-managed social media accounts, and the NPS Mobile App. The study's objectives are to describe the NPS virtual visitor population, understand their motivations, and determine which platforms are most effective. For one year, across four seasonal waves, this study will collect data through an online survey offered to NPS digital platform visitors.

The 21st Century Integrated Digital Experience Act, (44 U.S.C. 3501), was signed into law to improve the digital experience for government customers and reinforce existing requirements for federal public websites. The objectives of the NPS Virtual Visitor Study are to describe the NPS virtual visitor population, understand their motivations, determine which NPS digital assets and platforms are most effective, and identify where user needs are not being met to target resources for improvement. The results from this study will highlight the strengths and gaps in NPS digital offerings. Specifically, the study will inform a stronger virtual visitor monitoring program. A virtual visitor monitoring program will serve to measure the public's engagement and satisfaction with NPS digital assets over time.

Title of Collection: National Park Service Virtual Visitor Study.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: General public.

Total Estimated Number of Annual Respondents: 8,383.

Estimated Completion Time per Response: 7 minutes.

Total Estimated Number of Annual Burden Hours: 978 Hrs.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once (four seasonal survey waves over the course of one-year).

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2023–04917 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035450; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Pittsburg State University, Pittsburg, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Pittsburg State University has completed an inventory of human remains and associated funerary objects and has determined that there is no cultural affiliation between the human remains and any Indian Tribe. The human remains were removed from Kings County, CA; Luna County, NM; and Muskogee County, OK.

DATES: Disposition of the human remains in this notice may occur on or after April 10, 2023.

ADDRESSES: Steven Cox, Pittsburg State University, 1701 S Broadway, Pittsburg, KS 33732, telephone (620) 235–4883, email *spcox@pittstate.edu*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Pittsburg State University. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by Pittsburg State University.

Description

During the 1920s, human remains representing, at minimum, 19 individuals were removed by Harry Rimmer, an amateur archeologist, from locations reasonably believed to be Kings County, CA; Muskogee County, OK; and Luna County, NM. These human remains became part of the collection of the museum established at Pittsburg State University (then the Kansas Teachers College of Pittsburg) at the time of their removal. No records have survived concerning the acquisition or accession, identification, or age of these human remains. Articles about the museum published in the university's student newspaper in the 1920s reveal that in the mid-1920s, Dr. William Brandenburg, the president of the university, invited Harry Rimmer, to help establish a natural history museum at the university. During the following several years, Mr. Rimmer traveled throughout the U.S., excavated known Native American burial sites in Kings County, CA, Muskogee County, OK, and Luna County, NM, and removed and shipped human remains to the university for the museum. The museum existed on campus until approximately 1970. No known individuals were identified. No associated funerary objects are present.

Aboriginal Land

The human remains and associated funerary objects in this notice were removed from known geographic locations. These locations are the aboriginal lands of one or more Indian Tribes. The following information was used to identify the aboriginal land: treaties.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, Pittsburg State University has determined that:

- The human remains described in this notice represent the physical remains of 19 individuals of Native American ancestry.
- No relationship of shared group identity can be reasonably traced between the human remains and associated funerary objects and any Indian Tribe.
- The human remains described in this notice were removed from the aboriginal land of the Alabama-Quassarte Tribal Town; Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Cherokee Nation; Cheyenne and Arapaho Tribes, Oklahoma; Fort Sill Apache Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; The Muskogee (Creek) Nation; The Osage Nation; Tule River Indian Tribe of the Tule River Reservation, California; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma.

Requests for Disposition

Written requests for disposition of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for disposition may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization, or who shows that the requestor is an aboriginal land Indian Tribe.

Disposition of the human remains described in this notice to a requestor may occur on or after April 10, 2023. If competing requests for disposition are received, Pittsburg State University must determine the most appropriate requestor prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. Pittsburg State University is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9 and § 10.11.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04900 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035441; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Hudson Museum, University of Maine, Orono, ME

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Hudson Museum intends to repatriate a cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was removed from the Haines Borough, AK.

DATES: Repatriation of the cultural item in this notice may occur on or after April 10, 2023.

ADDRESSES: Amber Sky Heller, Registrar, Hudson Museum, University of Maine, 5746 Collins Center for the Arts, Orono, ME 04469, telephone (207) 581–1902, email *amber.sky.heller@maine.edu*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Hudson Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Hudson Museum.

Description

The cultural item was removed from the Haines Borough, AK. A drum was likely collected by Charlie Goldstein (1869–1961), who transferred it to his sister, Belle Simpson (nee Goldstein, 1885–1985), proprietor of The Nugget Shop in Juneau, Alaska. Around 1967, Morton D. May acquired the drum (along with other items in the Belle Simpson collection), and in 1970, William P. Palmer, III acquired it from May through Stendahl Galleries of Hollywood, CA. In 1982, Palmer bequeathed the drum to the University of Maine and it became part of the Hudson Museum's holdings. The one object of cultural patrimony is a Bentwood Box Drum (HM5523).

In June of 2018, a delegation from the Central Council of the Tlingit & Haida Indian Tribes came to the Hudson Museum for consultation. Subsequently, the Hudson Museum determined that this drum is affiliated with both the Central Council of the Tlingit & Haida Indian Tribes and the Ghaanaxhteidí clan of the Chilkat Indian Village (Klukwan).

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, geographical, historical, oral traditional, and other relevant information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Hudson Museum has determined that:

- The one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Central Council of the Tlingit & Haida Indian Tribes and the Chilkat Indian Village (Klukwan).

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the Hudson Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Hudson Museum is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04894 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035449; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Department of Environment and Conservation, Division of Archaeology, Nashville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Hardin, Lincoln, Madison, Obion, Perry, Tipton, and Williamson Counties, TN.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 10, 2023.

ADDRESSES: Phillip R. Hodge, Tennessee Department of Environment and Conservation, Division of Archaeology, 1216 Foster Avenue, Cole Building #3, Nashville, TN 37243, telephone (615) 626–2025, email *Phil.Hodge@tn.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the TDEC–DOA. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the TDEC–DOA.

Description

In 1969, human remains representing, at minimum, one individual were removed from site 40HR35 in Hardin County, TN, by archeologists associated with then Memphis State University (now the University of Memphis). In 1995, the human remains of this individual were accessioned into the TDEC–DOA's repository and transferred into its possession. No additional information is available regarding the curation history at the University of

Memphis nor the subsequent transfer to the TDEC–DOA. No known individual was identified. No associated funerary objects are present.

In 1975, human remains representing, at minimum, 24 individuals were removed from site 40LN16 in Lincoln County, TN, by archeologists with the TDEC–DOA prior to construction of the Lincoln County High School. The TDEC–DOA's 1975 excavations at this site were conducted under the permission of the landowner, the Lincoln County Board of Education. No known individuals were identified. The five associated funerary objects are one lot of shale fragments, one lot of fragments of a limestone-tempered ceramic vessel, one rectangular stone, one galena cube, and one lot of mica fragments.

In 1963, 1981, and 1983, human remains representing, at minimum, 24 individuals were removed from site 40MD1 in Madison County, TN, by archeologists with the TDEC–DOA. No known individuals were identified. The 1,524 associated funerary objects are 986 freshwater pearl beads, 529 marine columella beads, two bone rattles containing quartzite pebbles, two lithic fragments, one bone awl, one bone pin, one green schist pendant, one sheet of mica, and one green schist ''boatstone'' vessel.

In 1985, human remains representing, at minimum, 95 individuals were removed from site 40OB6 in Obion County, TN, by archeologists with Arrow Enterprises of Bowling Green, KY, under contract to the U.S. Soil Conservation Service. The human remains were accessioned into TDEC–DOA's repository the same year. No known individuals were identified. The 56 associated funerary objects are 25 marine shell beads, 11 pieces of lithic debitage, shatter, and fire-cracked rock, nine ceramic vessels, four ceramic sherds, one projectile point/knife, one piece of marine shell whelk, two lithic flakes, one stone effigy pipe, one carbon sample, and one stone discoidal.

Human remains representing, at minimum, 35 individuals were removed from Perry County, TN. Human remains belonging to 15 of these individuals were recovered from 40PY207 in secondary contexts along the Tennessee River by park rangers with Tennessee State Parks. These human remains were transferred to TDEC–DOA in 1991 and 1997. Human remains belonging to 17 of these individuals were excavated by Memphis State University between 1972 and 1976. No documentation is available to explain why these human remains were accessioned into TDEC–DOA's repository. No information exists regarding the provenance of the human remains belonging to three of these individuals or the circumstances under which they were accessioned into TDEC–DOA's repository. No known individuals were identified. The 24 associated funerary objects include 21 unidentified faunal long bones, two turkey tarsometatarsi, and one projectile point/knife.

Human remains representing, at minimum, one individual was removed from Tipton County, TN. The human remains had eroded from the bank of the Hatchie River at site 40TP1. They were found by rangers with the Hatchie National Wildlife Refuge on January 1, 1979, and were transferred the TDEC–DOA the same day. No known individual was identified. No associated funerary objects are present.

In 1979, human remains representing, at minimum, six individuals were removed from site 40WM33 in Williamson County, TN. These remains were excavated by volunteer avocational archeologists working under the auspices of the TDEC–DOA prior to road construction. The TDEC–DOA accessioned the human remains and an associated funerary object on December 11, 1979. No known individuals were identified. The one associated funerary object is a partially reconstructed ceramic jar.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical and historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the TDEC–DOA has determined that:

- The human remains described in this notice represent the physical remains of 186 individuals of Native American ancestry.
- The 1,610 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; The Chickasaw Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the TDEC–DOA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The TDEC–DOA is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04899 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035440; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Hudson Museum, University of Maine, Orono, ME

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and

Repatriation Act (NAGPRA), the Hudson Museum intends to repatriate certain cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Cattaraugus County, NY.

DATES: Repatriation of the cultural items in this notice may occur on or after April 10, 2023.

ADDRESSES: Amber Sky Heller, Registrar, Hudson Museum, University of Maine, 5746 Collins Center for the Arts, Orono, ME 04469, telephone (207) 581–1902, email *amber.sky.heller@maine.edu*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Hudson Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Hudson Museum.

Description

The three cultural items were removed from Cattaraugus County, NY. Sometime in the 1960s, three masks were removed from a long house on the Allegheny Reservation prior to the building's inundation by the Kinzua Dam. In 1969, the three masks were purchased by the University of Maine from Sheldon M. Tucker, M.D., of Houston, TX. Dr. Richard Emerick, founding Director, coordinated the purchase of the masks for the University's Anthropology Museum, which became the Hudson Museum in 1986. The three objects of cultural patrimony are a Wolf Clan Mask (HM4838), a Consolation Mask (HM4839), and a New Year's Ceremonial Mask (HM4840).

In March of 2020, the Hudson Museum began consultation with Dr. Joe Stahlman, Director of the Seneca-Iroquois National Museum and Tribal Historic Preservation Officer for the Seneca Nation of Indians. Subsequently, the Hudson Museum determined that the masks are culturally affiliated with the Coldspring Longhouse of the Seneca Nation of Indians.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, geographical, historical, and other relevant information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Hudson Museum has determined that:

- The three cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Seneca Nation of Indians.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the Hudson Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Hudson Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04893 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035442; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Hudson Museum, University of Maine, Orono, ME

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Hudson Museum intends to repatriate a cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was removed from Wrangell Borough, AK.

DATES: Repatriation of the cultural items in this notice may occur on or after April 10, 2023.

ADDRESSES: Amber Sky Heller, Registrar, Hudson Museum, University of Maine, 5746 Collins Center for the Arts, Orono, ME 04469, telephone (207) 581–1902, email *amber.sky.heller@maine.edu*.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Hudson Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Hudson Museum.

Description

The cultural item was removed from Wrangell Borough, AK. At an unknown date, Proctor Stafford acquired a helmet from an unidentified woman living in Honolulu, HI. Subsequently, William P. Palmer, III purchased it from Stafford. In 1982, Palmer bequeathed this object to the University of Maine and it became part of the Hudson Museum's holdings. The object of cultural patrimony is a Frog Clan helmet (HM5040).

In June of 2018, a delegation from the Central Council of Tlingit and Haida Indian Tribes of Alaska came to the Hudson Museum for consultation. Subsequently, the Hudson Museum determined that this helmet is culturally affiliated with both the Central Council of Tlingit and Haida Indian Tribes of Alaska and the Kiks.ádi clan of the Wrangell Cooperative Association.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, historical, oral traditional, other relevant information, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Hudson Museum has determined that:

- The one cultural item described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Central Council of the Tlingit & Haida Indian Tribes and the Wrangell Cooperative Association.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the Hudson Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Hudson Museum is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04895 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035443; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California San Diego, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California San Diego has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from San Diego County, CA.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 10, 2023.

ADDRESSES: Eva Trujillo, University of California San Diego, 9500 Gilman Drive, La Jolla, CA 92093, telephone (858) 414–4609, email *e7trujillo@ucsd.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California San Diego. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the University of California San Diego.

Description

Human remains representing, at minimum, one individual were removed from the Shumway Lot of the Scripps Estates in La Jolla, San Diego County, CA. This location is identified as Hubbs site number ''1958:XII:13 (A) SEA. (Scripps Estates) Shumway Lot.'' In 1958, Dr. Carl Leavitt Hubbs, an employee of the University of California, San Diego/Scripps Institution of Oceanography (UCSD), removed the human remains and associated funerary objects from the site. The 19 associated funerary objects are one lot of chipped stone, one lot of modified faunal material, five lots of modified shell, one lot of pebbles, one lot of plant leaf fragments, one lot of soil, two lots of unmodified faunal material, and seven lots of unmodified shell.

Human remains representing, at minimum, one individual were removed from Spindrift Drive of the Scripps Estates in La Jolla, San Diego County, CA. This location is identified as Hubbs site number ''1961:IX:28A Dec 6'' and ''Spindrift Drive Midden Dec VI (W–1).'' In 1961, Dr. Carl Leavitt Hubbs of UCSD removed the human remains and associated funerary objects from the site. The five associated funerary objects are one lot of ceramic sherds, one lot of charcoal, one lot of stone, one lot of unmodified faunal material, and one lot of unmodified shell.

Human remains representing, at minimum, one individual were removed from Holter's Lot of the Scripps Estates in La Jolla, San Diego County, CA. This location is identified as Hubbs site number ''1964:IV:Holters Lot Box 6.'' In 1964, Dr. Carl Leavitt Hubbs of UCSD removed the human remains and associated funerary objects from the site. The five associated funerary objects are one lot of chipped stone, one fishing weight, one metate fragment, one lot of pebbles and gravel, and one lot of unmodified shell.

Human remains representing, at minimum, one individual were removed from the Scripps Estates in La Jolla, San Diego County, CA. This location is identified as Hubbs site number ''SMT 2 (maybe SMT 1) and Isaac's Lot.'' In 1958–1959, Dr. Carl Leavitt Hubbs of UCSD removed the human remains and associated funerary objects from the site. The 17 associated funerary objects are one chipped stone biface, two lots of lithics, two lots of plant matter, one small volcanic stone, one lot of stones, four lots of unmodified faunal material, and six lots of unmodified shell.

Human remains representing, at minimum, one individual were removed from the Scripps Estates in La Jolla, San Diego County, CA. This location is identified as Hubbs site number ''SDI–525 Pit 6.'' In 1958–1959, Dr. Carl Leavitt Hubbs of UCSD removed the human remains and associated funerary objects from the site. The 14 associated funerary objects are one lot of modified faunal material, three lots of pebbles, three lots of plant matter, one shell

pendant, two lots of unmodified faunal material, and four lots of unmodified shell.

The human remains and associated funerary objects listed in this notice were incorporated into what became known as the ''Hubbs Collection.'' In 1973, Dr. Hubbs bequeathed the Hubbs Collection to the Museum of Us (formerly the San Diego Museum of Man). In March of 2004, the Museum of Us (MoU) deaccessioned the Hubbs Collection and donated it to the University of San Diego (USD) Anthropology Department, although some of the collection remained at the MoU. In June of 2020, the University of California, San Diego (UCSD) became aware of the Hubbs Collection and, in December 2020, given the scope of the collection and complexities related to provenance, UCSD, MoU, and USD reached an agreement to work together to facilitate NAGPRA compliance.

Cultural Affiliation

The human remains and associated funerary objects described in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological information, archeological information, geographical information, historical information, and oral tradition.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the University of California San Diego, CA, has determined that:

- The human remains described in this notice represent the physical remains of five individuals of Native American ancestry.
- The 60 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (*previously* listed as Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and the Sycuan Band of the Kumeyaay Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the University of California San Diego must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of California San Diego is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04896 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035439; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion Amendment: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC

AGENCY: National Park Service, Interior.

ACTION: Notice; amendment.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Indian Affairs (BIA) has amended a Notice of Inventory Completion published in the **Federal Register** on April 10, 2013. This notice amends the cultural affiliation of a collection removed from San Juan County, UT.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after April 10, 2023.

ADDRESSES: Tamara Billie, NAGPRA Coordinator, Bureau of Indian Affairs, 1001 Indian School Road NW, Mailbox 44—Suite 345, Albuquerque, NM 87104, telephone (505) 879–9711, email *tamara.billie@bia.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the BIA. The National Park Service is not responsible for the determinations in this notice. Additional information on the amendments and determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the BIA.

Amendment

This notice amends the determinations published in a Notice of Inventory Completion in the **Federal Register** (78 FR 21408–21409, April 10, 2013). Repatriation of the items in the original Notice of Inventory Completion has not occurred. The human remains and associated funerary objects are under the control of the BIA and in the physical custody of the University of Denver Museum of Anthropology. The human remains and associated funerary objects were removed from a site referenced as UT W:10:2, located south of the town of Bluff, in San Juan County, UT, and on the Navajo Indian Reservation. Based on geographic evidence, officials of the BIA have

determined that the Native American human remains are culturally affiliated with the Navajo Nation, Arizona, New Mexico, & Utah.

Determinations (as Amended)

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the BIA has determined that:

- The human remains described in this amended notice represent the physical remains of one individual of Native American ancestry.
- The 47 objects described in this amended notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Navajo Nation, Arizona, New Mexico, & Utah.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the BIA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The BIA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, 10.13, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04892 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0035448; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Mukwonago Community Library, Mukwonago, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Mukwonago Community Library intends to repatriate a cultural item that meets the definition of an unassociated funerary object and that has a cultural affiliation with the Indian Tribes in this notice. The cultural item was removed from Sacramento County, CA.

DATES: Repatriation of the cultural item in this notice may occur on or after April 10, 2023.

ADDRESSES: Abby Armour, Mukwonago Community Library, 511 Division St., Mukwonago, WI 53149, telephone (262) 363–6411, email *nagpra@mukwonagolibrary.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Mukwonago Community Library. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Mukwonago Community Library.

Description

The one cultural item was removed from Hollister Mound in Sacramento County, CA. It was bequeathed to the Mukwonago Community Library by Arthur Grutzmacher, a local collector and dealer, following his death in 1965. The unassociated funerary object is one lot of shell beads (G01124).

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical and historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, the Mukwonago Community Library has determined that:

- The one cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and is believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Wilton Rancheria, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe.

Repatriation of the cultural item in this notice to a requestor may occur on or after April 10, 2023. If competing requests for repatriation are received, the Mukwonago Community Library must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Mukwonago Community Library is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: March 1, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–04898 Filed 3–9–23; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–685 and 731–TA–1599–1606 (Preliminary)]

Tin Mill Products From Canada, China, Germany, Netherlands, South Korea, Taiwan, Turkey, and United Kingdom

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 there is a reasonable indication that an industry in the United States is materially injured by reason of imports of tin mill products from Canada, China, Germany, Netherlands, South Korea, Taiwan, Turkey, and United Kingdom, provided for in subheadings 7210.11.00, 7210.12.00, 7210.50.00, 7212.10.00, 7212.50.00, 7225.99.00, and 7226.99.01 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On January 18, 2023, Cleveland-Cliffs, Cleveland, Ohio, and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (''United Steelworkers'' or ''USW''), Pittsburgh, Pennsylvania, filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of tin mill products from China and LTFV imports of tin mill products from Canada, China, Germany, Netherlands, South Korea, Taiwan, Turkey, and United Kingdom. Accordingly, effective January 18, 2023, the Commission instituted countervailing duty investigation No. 701–TA–685 and antidumping duty investigation Nos. 731–TA–1599–1606 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference 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** of January 24, 2023 (88 FR 4206). The Commission conducted its conference on February 8, 2023. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on March 6, 2023. The views of the Commission are contained in USITC Publication 5413 (March 2023), entitled *Tin Mill Products from Canada, China, Germany, Netherlands, South Korea, Taiwan, Turkey, and United Kingdom: Investigation Nos. 701–TA–685 and 731–TA–1599–1606 (Preliminary).*

By order of the Commission.

Issued: March 6, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–04862 Filed 3–9–23; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 88 FR 9476 and 88 FR 9481, February 14, 2023.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2022–0007]

McNally/Kiewit Joint Venture: Grant of Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of permanent variance.

SUMMARY: In this notice, OSHA grants a permanent variance to McNally/Kiewit Joint Venture (McNally) related to work in compressed-air environments.

DATES: The permanent variance specified by this notice becomes effective on March 10, 2023 and shall remain in effect until the completion of the Shoreline Storage Tunnel project or until modified or revoked by OSHA.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, phone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and Technical Information: Contact Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; phone: (202) 693–2110 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

*Copies of this **Federal Register** notice:* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice and other relevant information are also available at OSHA's web page at *http://www.osha.gov.*

I. Overview

On November 12, 2021, OSHA received a variance application submitted by letter from McNally/Kiewit joint venture (''McNally'' or ''the applicant'') regarding the Shoreline Storage Tunnel project, which consists of boring a 12-foot diameter tunnel under a subaqueous roadway in Cleveland, Ohio. McNally requested a permanent variance from several provisions of 29 CFR 1926.803, the OSHA standard that regulates construction work in compressed air environments. Specifically, McNally sought a variance from the provisions of the standard that: (1) prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an

emergency (29 CFR 1926.803(e)(5)); [1] (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively). McNally also requested an interim order pending OSHA's decision on the application for a variance (Document ID No. OSHA–2022–0007–0002).

OSHA reviewed McNally's application for a permanent variance and interim order and determined that it was appropriately submitted in compliance with the applicable variance procedures in Section 6(d) of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 655) and OSHA's regulations at 29 CFR 1905.11 (variances and other relief under section 6(d)), including the requirement that the applicant inform workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

OSHA reviewed the alternative procedures in McNally's application and preliminarily determined that the applicant's proposed alternatives on the whole, subject to the conditions in the request and imposed by the interim order, provide measures that are as safe and healthful as those required by the cited OSHA standards. On September 26, 2022, OSHA published a **Federal Register** notice announcing McNally's application for permanent variance, stating the preliminary determination along with the basis of that determination, and granting the interim order (87 FR 58379). OSHA requested comments on each.

OSHA did not receive any comments or other information disputing the preliminary determination that the alternatives were at least as safe as OSHA's standard, nor any objections to OSHA granting a permanent variance. Accordingly, through this notice OSHA grants a permanent variance, subject to the conditions set out in this document.

A. Background

The information that follows about McNally, its methods, and its project comes from McNally's variance application.

McNally (the applicant) is a contractor that works on complex tunnel projects using innovations in tunnel-excavation methods and is the contractor for the Shoreline Storage Tunnel Project (the project). The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balanced tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

McNally asserts that it bores tunnels using a TBM at levels below the water table through soft soils consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

McNally's Hyberbaric Operations Manual (HOM) for the Shoreline Storage Tunnel Project indicated that the maximum pressure to which it is likely to expose workers during project interventions for the Shoreline Storage Tunnel Project is 55 p.s.i. Therefore, to work effectively, McNally must perform hyperbaric interventions in compressed air at pressures nearly 10% higher than the maximum pressure specified by the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: ''No employee shall be subjected to pressure exceeding 50 p.s.i. except in emergency'' (see footnote 1).

McNally employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, McNally asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 55 p.s.i., which exceeds the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head. These interventions are the only time that workers are exposed to compressed air. Interventions in the working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the permanent variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

McNally asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and would thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803.

[1] The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by 29 CFR 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, McNally asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, would deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(e)(5) and (f)(1) and the decompression tables in Appendix A of 29 CFR 1926, subpart S. Nevertheless, according to McNally, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

McNally contends that the alternative safety measures included in the application provide McNally's workers with a place of employment that is at least as safe under its proposed alternatives as they would be under OSHA's compressed-air standard for construction. McNally also provided OSHA a project-specific HOM, (OSHA–2022–0007–0003) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers to support their assertions of equivalency in worker protection.

OSHA included all of the above information in the **Federal Register** notice regarding McNally's variance application and did not receive any comments disputing any of that information, including the safety assertions made by McNally in the Variance application.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR 1905.11), the applicant has certified that it notified its workers [2] of the variance modification application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant has certified that it informed its workers of their right to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance modification application.

[2] See the definition of ''Affected employee or worker'' in section VII.C. of this Notice.

III. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted five subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the completion of the Anacostia River Tunnel in Washington, DC (80 FR 50652 (August 20, 2015)); (2) Traylor JV for the completion of the Blue Plains Tunnel in Washington, DC (80 FR 16440 (March 27, 2015)); (3) Tully/OHL USA Joint Venture for the completion of the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809 (May 23, 2014)); (4) Salini/Impregilo/Healy Joint Venture for the completion of the Northeast Boundary Tunnel in Washington, DC (85 FR 27767 (May 11, 2020)); and (5) Ballard Marine Construction for the completion of the Suffolk County Tunnel Project in Suffolk, New York (86 FR 5253 (January 19, 2021)). OSHA has also granted interim orders to two applicants, Ballard Marine for the Suffolk County Outfall Tunnel project in West Babylon, New York (86 FR 5253 (January 19, 2021)) and Traylor Shea Joint Venture for the Alexandria RiverRenew Tunnel Project in Alexandria, Virginia and Washington, DC (87 FR 54536 (September 6, 2022)). The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances.[3] OSHA is not aware of any injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

IV. Applicable OSHA Standard and the Relevant Variances

A. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure to Pressure Greater Than 50 p.s.i.g. (See Footnote 1)

The applicant states that it may perform hyperbaric interventions at pressures up to 55 p.s.i.g. in the working chamber of the TBM; this pressure exceeds the pressure limit of 50 p.s.i. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The TBM has twin man-locks, with each man-lock having two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the staging chamber and the forward working chamber. The staging chamber is the section of the working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

McNally will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that they may have to perform interventions at pressures up to 55 p.s.i.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (*i.e.,* when decompression times are greater than work times), the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

Further, McNally has developed a project-specific HOM (OSHA–2022–0007–0003) that describes in detail the hyperbaric procedures, the required medical examination used during the tunnel-construction project, the standard operating procedures and the

[3] The previous tunnel construction variances allowed further deviation from OSHA standards by permitting employee exposures above 50 p.s.i. based on the composition of the soil and the amount of water that will be above the tunnel for various sections of this project. The current proposed variance includes substantively the same safeguards as the variances that OSHA granted previously even though employees will not be exposed to pressures higher than 55 p.s.i.g.

emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor (a competent person experienced and trained in hyperbaric operations, procedures and safety) and attending physician. In addition, procedures include medical screening and review of prospective compressed-air workers (CAWs). The purpose of this screening procedure is to vet prospective CAWs with medical conditions (*e.g.,* deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (*e.g.,* a man-lock) for extended periods, or by exposure to elevated pressures and compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i. or 50 p.s.i.g.

OSHA comprehensively reviewed the project-specific HOM and determined that the safety and health instructions and measures it specifies are appropriate, conform with the conditions in the variance, and adequately protect the safety and health of the CAWs.

B. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).[4] The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Shoreline Storage Tunnel-specific Hyperbaric Operations Manual (HOM) are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926, subpart S. Accordingly, the applicant commits to following the decompression procedures described in that HOM, which would require it to follow the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. McNally asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician, certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant also will be present during hyperbaric exposures and decompression. This man-lock attendant will operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

C. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

McNally is applying for a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolves in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as ''the bends.'' This description of the etiology of DCI is consistent with current scientific theory and research on the issue (see footnote 16 in this notice discussing a 1985 NIOSH report on DCI).

The 1992 French Decompression Tables, proposed for use by the applicant provide for stops during worker decompression (*i.e.,* staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.[5] In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as

[4] In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

[5] See, *e.g.,* Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine,* 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression for compressed-air work was in some cases at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, ''Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . ., which provides less and less meaningful bubble suppression . . . .'' In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that ''[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control.''

effective as an automatic controller in regulating the decompression process because the HOM includes a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

D. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an additional special decompression lock or chamber. The applicant proposes that it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all exposed workers during decompression. The applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

V. Decision

After reviewing the proposed alternatives, OSHA has determined that the applicant's proposed alternatives on the whole, subject to the conditions in the variance request and imposed by the permanent variance, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section II of this notice.

In addition, OSHA has determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(e)(5)

McNally has developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i. The alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i. while engaged in the construction of a subaqueous tunnel using advance shielded mechanical-excavation techniques in conjunction with the TBM. Prior to conducting interventions in the TBM's pressurized working chamber, McNally halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. 29 CFR 1926.803(f)(1)

The applicant has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.,* staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the five previous permanent variances to IHP JV, Traylor JV, Tully JV, Salini-Impregilo Joint Venture, and Ballard, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.,* the 1992 French Decompression Tables) McNally proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions outlined in this variance application.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard. For example, H. L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).[6] This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H. L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.[7]

OSHA's experience with the previous five variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provide evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans[8] that either granted

[6] Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine,* 29(3), pp. 172–188.

[7] Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS,* pp. 1–5 (see Ex. OSHA–2012–0036–0005).

[8] Under Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories

variances (Nevada, Oregon and Washington) [9] or promulgated a new standard (California) [10] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, provide additional evidence of the effectiveness of this alternative procedure.

C. 29 CFR 1926.803(g)(1)(iii)

The applicant developed, and proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent—and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this preliminary conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of State Plan States, and a review of the literature and other information noted earlier.

D. 29 CFR 1926.803(g)(1)(xvii)

The applicant developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times exceeding 75 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Based on a review of available evidence, the experience of State Plans that either granted variances (Nevada, Oregon, and Washington) [11] or promulgated a new standard (California) [12] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Pursuant to Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the agency finds that when the McNally complies with the conditions of the following order, the working conditions of the McNally's workers are at least as safe and healthful as if it complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, McNally must: (1) comply with the conditions listed below under ''Conditions Specified for the Permanent Variance'' for the period between the date of this notice and completion of the Shoreline Storage Tunnel Project; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of the application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) completion of the Shoreline Storage Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

VI. Description of the Conditions Specified for the Permanent Variance

The conditions for the variance are set out in the Order at the end of this document. This section provides additional detail regarding the conditions in the Order.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified under this condition. Clearly defining the scope of the permanent variance provides McNally, their employees, potential future applicants, other stakeholders, the public and OSHA with necessary information regarding the work situations in which the permanent variance applies. To the extent that McNally exceeds the defined scope of this variance, it will be required to comply with OSHA's standards. This permanent variance applies only to McNally, and only to the remainder of the Cleveland Storage Tunnel Project.

Condition B: List of Abbreviations

Condition B defines a number of abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and their employees' understanding of the conditions specified by the permanent variance.

Condition C: Definitions

Condition C defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and their employees' understanding of the conditions specified by the permanent variance.

Condition D: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA an HOM specific to the Shoreline Storage Tunnel at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested marked, and stamped in accordance with the requirements for ASME PVHO–1–2019 (or the most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM to OSHA, which McNally has already completed, enables OSHA to determine that the specific safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO–1–2019 is intended

may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as ''State Plans.'' Occupational safety and health standards developed by State Plans must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

[9] These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

[10] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

[11] These state variances are available in the application docket for the original Traylor variance application: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0007 (Oregon), and OSHA–2012–0035–0008 (Washington).

[12] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure.

Additionally, the condition includes a series of related hazard prevention and control requirements and methods (*e.g.,* decompression tables, job hazard analysis (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition E: Communication

Condition E requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication ensures that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires McNally to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Condition F: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work ensures that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition also requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if they believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Condition G: Inspections, Tests, and Accident Prevention

Condition G requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the job site for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition H: Compression and Decompression

This condition requires the applicant to consult with a designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical advisor. This provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Condition I: Recordkeeping

Under OSHA's existing recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore McNally must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding question on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (*e.g.,* air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15

- time of symptom onset;
- duration between decompression and onset of symptoms

Q16

- type and duration of symptoms;
- a medical summary of the illness or injury

Q17

- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.[13]

Condition I adds additional reporting responsibilities, beyond those already required by the OSHA rule. McNally is required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under Condition J (using OSHA's Form

[13] See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses *(http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631)*; recordkeeping forms and instructions *(http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf)*; and OSHA Recordkeeping Handbook *(http://www.osha.gov/recordkeeping/handbook/index.html).*

301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, and 1904.8–.12), enables McNally and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition J: Notifications

Under the notification condition, the applicant is required, within specified periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations; (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the Cleveland OSHA Area Office within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect McNally's ability to comply with the conditions of the modified permanent variance; and (6) provide OTPCA and the Cleveland Ohio OSHA Area Office, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the modified permanent variance in providing the requisite level of safety to the applicant's workers and, based on this assessment, whether to revise or revoke the conditions of the modified permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the modified permanent variance to a successor company. In addition, the condition specifies that the transfer of the modified permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the modified permanent variance and expedite the agency's administration and enforcement of the modified permanent variance. Stipulating that an applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by modified permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the modified permanent variance.

VII. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on September 26, 2022 and replacing it with a permanent variance order. Note that there are not any substantive changes in the conditions between interim order and the final order.

OSHA issues this final order authorizing McNally to comply with the following conditions instead of complying with the requirements of 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). These conditions are:

A. Scope

The permanent variance applies only when McNally stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.,* inspection, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Shoreline Storage Tunnel Project in Cleveland, Ohio, a subaqueous tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an TBM;

2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and

3. Performed in compliance with all applicable provisions of 29 CFR 1926 except for the requirement specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii).

4. This order will remain in effect until one of the following conditions occurs: (1) completion of the Shoreline Storage Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. List of Abbreviations

Abbreviations used throughout this permanent variance include the following:

1. COAO—Cleveland, Ohio OSHA Area Office
2. CAW—Compressed-air worker
3. CFR—Code of Federal Regulations
4. DCI—Decompression Illness
5. TBM—Earth Pressure Balanced Moving Tunnel Boring Machine
6. HOM—Hyperbaric Operations and Safety Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

C. Definitions

The following definitions apply to this permanent variance. These definitions supplement the definitions in McNally's project-specific HOM.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term ''employee'' has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 p.s.i.a., 1 atmosphere absolute, or 0 p.s.i.g.

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 55 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[14]

5. *Decompression illness (also called decompression sickness or the bends)*—an illness caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include (but are not limited to): joint pain (also known as the ''bends'' for agonizing pain or the ''niggles'' for slight pain); areas of bone destruction (termed ''dysbaric osteonecrosis''); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).[15]

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O_2) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Moving Tunnel Boring Machine*—the machinery used to excavate the tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.[16]

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by the McNally for working in compressed air during the Shoreline Storage Tunnel.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into or out of a working chamber.

14. *Medical Advisor*—medical professional experience in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area; usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

17. *p.s.i.a*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea level, atmospheric pressure is approximately 14.7 p.s.i. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

18. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea level, atmospheric pressure is approximately 14.7 p.s.i. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g.

19. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[17]

20. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man lock.

D. Safety and Health Practices

1. McNally must implement the project-specific HOM submitted to OSHA as part of the variance application (see OSHA–2022–0007–0003). The HOM provides the minimum requirements regarding expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. McNally must demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked and stamped in accordance with the requirements of ASME PVHO–1.2019 (or most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. McNally must implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. McNally must ensure that there are no exposures to pressures greater than 55 p.s.i.g.

5. McNally must ensure that air or oxygen as the only breathing gas in the working chamber.

6. McNally must follow the 1992 French Decompression Tables for air, air-oxygen, and oxygen decompression specified in the HOM, specifically the tables titled ''French Regulation Air Standard Tables.''

7. McNally must equip man-locks used by their employees with an oxygen-delivery system as specified by the HOM. McNally is prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, McNally must maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. McNally must develop and implement one or more Job Hazard Analyses (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.,* after making changes to a planned intervention that affects their operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk

[14] Adapted from 29 CFR 1926.32(f).

[15] See Appendix 10 of ''A Guide to the Work in Compressed Air Regulations 1996,'' published by the United Kingdom Health and Safety Executive and available from NIOSH at *http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf.*

[16] Also see 29 CFR 1910.146(b).

[17] Adapted from 29 CFR 1926.32(m).

assessment [18] indicates are essential to prevent injury or illness.

11. McNally must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by this permanent variance (including all procedures required by the HOM, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. McNally must ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.[19]

E. Communication

1. Prior to beginning a shift, McNally must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rockslides, cave-ins, flooding, fires, or explosions.

2. McNally must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) McNally must use an independent power supply for powered communication systems, and these systems must operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) McNally must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

F. Worker Qualification and Training

McNally must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, in hyperbaric conditions, and document this instruction. The instruction must include topics such as:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (*e.g.,* barotrauma, nitrogen narcosis, and oxygen toxicity).

(d) How to avoid discomfort during compression and decompression; and

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (2) of this condition periodically and as necessary (*e.g.,* after making changes to their hyperbaric operations).

4. When conducting training for their hyperbaric workers, make this training available to OSHA personnel and notify OTPCA the Cleveland, Ohio OSHA Area Office before the training takes place.

G. Inspections, Tests, and Accident Prevention

1. McNally must initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks, as well as weekly inspections of the TBM.

2. Remove from service any equipment that constitutes a safety hazard until it corrects the hazardous condition and has the correction approved by a qualified person.

3. McNally must maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job site for the duration of the job.

H. Compression and Decompression

McNally must consult with their attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

I. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, McNally must maintain records of:

1. The date, times (*e.g.,* time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

J. Notifications

1. To assist OSHA in administering the conditions specified herein, the McNally must:

(a) Notify the OTPCA and the Cleveland Ohio OSHA Area Office of any recordable injury, illness, or fatality (by submitting the completed OSHA's Form 301 Injury and Illness Incident Report form) [20] resulting from exposure of an employee to hyperbaric conditions, including those exposures that do not require recompression treatment (*e.g.,* nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The employer shall provide the notification within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality, and submit a copy of the incident investigation (OSHA's Form 301 Injury and Illness Injury Reporting Form) within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information

[18] See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

[19] See ANSI/ASSE A10.33–2011, American National Standard for Construction and Demolition Operations—Safety and Health Program Requirements for Multi-Employer Projects, for reference.

[20] See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (*http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631*); recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and the OSHA Recordkeeping Handbook (*http://www.osha.gov/recordkeeping/handbook/index.html*).

required by the OSHA's Form 301 Injury and Illness Injury Reporting Form, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification within 15 days of the incident that the employer informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the Cleveland Ohio OSHA Area Office within 15 working days in writing of any change in the compressed-air operations that affects the employer's ability to comply with the conditions specified herein.

(d) Upon completion of the Shoreline Storage Tunnel, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the Cleveland Ohio OSHA Area Office.

Note: The evaluation report is to contain summaries of: (1) the number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA's Form 301 Injury and Illness Incident Report and OSHA's Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the Cleveland Ohio OSHA Area Office as soon as possible after it has knowledge that it will:

i. Cease to do business;

ii. Change the location and address of the main office for managing the tunneling operations specified herein; or

iii. Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of the application for a variance.

(g) This permanent variance cannot be transferred to a successor company without OSHA approval.

OSHA hereby grants a permanent variance to McNally to the provisions of 29 CFR 1926.803 outlined in this notice.

VIII. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(d), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1905.11.

Signed at Washington, DC, on March 6, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–04883 Filed 3–9–23; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2022–0009]

Traylor-Shea Joint Venture: Grant of Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA grants a permanent variance to Traylor-Shea Joint Venture (TSJV) related to work in compressed air environments.

DATES: The permanent variance specified by this notice becomes applicable on March 10, 2023 and shall remain in effect until the completion of the Alexandria RiverRenew Tunnel project or until modified or revoked by OSHA.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

*Copies of this **Federal Register** notice.* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at *http://www.osha.gov.*

I. Overview

On March 15, 2021, Traylor Bros., Inc. (Traylor) submitted an application by letter to modify the permanent variance granted to Traylor on March 11, 2016 (2016 Variance) (81 FR 12954) to include an additional employer, the Traylor Shea Joint Venture (TSJV), which is a joint venture made up of two construction companies; Traylor and J.F. Shea Construction, Inc. (Shea). TSJV was awarded the tunneling contract for the Alexandria RiverRenew Tunnel Project in Alexandria, Virginia and Washington, DC (OSHA–2022–0009–0002). TSJV also requested an Interim Order while OSHA evaluates the application (OSHA–2022–0009–0005). Because the joint venture includes an additional employer not covered by the previously issued permanent variance, OSHA has evaluated the modification request as an application for a new permanent variance. This notice covers the Alexandria RiverRenew tunneling project only and is not applicable to future tunneling projects by Traylor, Shea, or TSJV.

This notice addresses the application by TSJV (the applicant) for a permanent variance and interim order from the provisions of the standard governing compressed air work that: (1) prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an emergency (29 CFR 1926.803(e)(5)); [1] (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and (g)(1)(xvii), respectively).

OSHA reviewed TSJV's application for the variance and interim order and determined that they were appropriately submitted in compliance with the applicable variance procedures in Section 6(d) of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 655) and OSHA's regulations at 29 CFR 1905.11 (Variances and other relief under section 6(d)), including the requirement that the applicant inform

[1] The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by § 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

OSHA reviewed the alternative procedures in TSJV's application and preliminarily determined that the applicant's proposed alternatives on the whole, subject to the conditions in the request and imposed by the Interim Order, provide measures that are as safe and healthful as those required by the cited OSHA standards. On September 6, 2022, OSHA published a **Federal Register** notice announcing TSJV's application for permanent variance, stating the preliminary determination along with the basis of that determination, and granting the Interim Order (87 FR 54536). OSHA requested comments on each.

OSHA did not receive any comments or other information disputing the preliminary determination that the alternatives were at least as safe as OSHA's standard, nor any objections to OSHA granting a permanent variance. Accordingly, through this notice OSHA grants a permanent variance, subject to the conditions set out in this document.

A. Background

The information that follows about TSJV, its methods, and the Alexandria RiverRenew Project comes from the TSJV variance application.

TSJV is a contractor for the Alexandria RiverRenew Tunnel Project (the project), that works on complex tunnel projects using innovations in tunnel-excavation methods. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balance tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

TSJV asserts that it bores tunnels using a TBM at levels below the water table through soft soils consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

TSJV's Hyperbaric Operations Manual (HOM) for the Alexandria RiverRenew Project indicated that the maximum pressure to which it is likely to expose workers during project interventions for the Alexandria RiverRenew Tunnel Project is 52.5 p.s.i. Therefore, to work effectively, TSJV must perform hyperbaric interventions in compressed air at pressures nearly 5% higher than the maximum pressure specified by the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: ''No employee shall be subjected to pressure exceeding 50 p.s.i. except in emergency'' (see footnote 1).

TSJV employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, TSJV asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 52.5 p.s.i., which exceeds the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head. These interventions are the only time that workers are exposed to compressed air. Interventions in the working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the permanent variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

TSJV asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and would thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, TSJV asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, would deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(e)(5) and (f)(1) and the decompression tables in Appendix A of 29 CFR 1926, subpart S. Nevertheless, according to TSJV, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

TSJV contends that the alternative safety measures included in the application provide TSJV's workers with a place of employment that is at least as safe under its proposed alternatives as they would be under OSHA's compressed-air standard for construction. TSJV also provided OSHA a project-specific HOM, (OSHA–2022–0009–0002) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers to support their

assertions of equivalency in worker protection.

OSHA included all of the above information in the **Federal Register** notice announcing TSJV's variance application and did not receive any comments disputing any of that information, including the safety assertions made by TSJV in the variance application.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR 1905.11), the applicant has certified that it notified its workers [2] of the variance application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant has certified that it informed its workers of their right to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

III. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted five subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the completion of the Anacostia River Tunnel in Washington, DC (80 FR 50652 (August 20, 2015)); (2) Traylor JV for the completion of the Blue Plains Tunnel in Washington, DC (80 FR 16440 (March 27, 2015)); (3) Tully/OHL USA Joint Venture for the completion of the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809 (May 23, 2014)); and (4) Salini-Impregilo/Healy Joint Venture for the completion of the Northeast Boundary Tunnel in Washington, DC (85 FR 27767, (May 11, 2020)). OSHA also granted an Interim Order to Ballard Marine for the Suffolk County Outfall Tunnel project in West Babylon, New York (86 FR 5253 (January 19, 2021)). The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances.[3] OSHA is not aware of any injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

IV. Applicable OSHA Standard and the Relevant Variance

A. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure to Pressure Greater Than 50 p.s.i.

The applicant states that it may perform hyperbaric interventions at pressures greater than 50 p.s.i. in the working chamber of the TBM; this pressure exceeds the pressure limit of 50 p.s.i. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The TBM has twin man-locks, with each man-lock having two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the staging chamber and the forward working chamber. The staging chamber is the section of the working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

TSJV will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that they may have to perform interventions at pressures up to 52.5 p.s.i.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (*i.e.,* when decompression times are greater than work times), the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

Further, TSJV has developed a project-specific HOM (OSHA–2022–0009–0003) that describes in detail the hyperbaric procedures, the required medical examination used during the tunnel-construction project, the standard operating procedures and the emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor (a competent person experienced and trained in hyperbaric operations, procedures and safety) and attending physician. In addition, procedures include medical screening and review of prospective compressed-air workers (CAWs). The purpose of this screening procedure is to vet prospective CAWs with medical conditions (*e.g.,* deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (*e.g.,* a man-lock) for extended periods or by exposure to elevated pressures and compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i. or 50 p.s.i.g.

OSHA comprehensively reviewed the project-specific HOM and determined that the safety and health instructions and measures it specifies are appropriate and adequately protect the safety and health of the CAWs.

[2] See the definition of ''Affected employee or worker'' in section VI.C of this Notice.

[3] The previous tunnel construction variances allowed further deviation from OSHA standards by permitting employee exposures above 50 p.s.i..based on the composition of the soil and the amount of water that will be above the tunnel for various sections of this project. The current permanent variance includes substantively the same safeguards as the variances that OSHA granted previously even though employees will not be exposed to pressures higher than 52.5 p.s.i.g.

B. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).[4] The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Alexandria RiverRenew Tunnel Project-specific HOM are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926 subpart S. Accordingly, the applicant commits to following the decompression procedures described in that HOM, which requires TSJV to follow the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. Traylor asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician, certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant is also required to be present during hyperbaric exposures and decompression. This man-lock attendant is to operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, who is trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

C. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

TSJV is applying for a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as ''the bends.'' This description of the etiology of DCI is consistent with current scientific theory and research on the issue (see footnote 16 in this notice discussing a 1985 NIOSH report on DCI).

The 1992 French Decompression Tables, proposed for use by the applicant, provide for stops during worker decompression (*i.e.,* staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.[5] In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM includes a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

D. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an additional special decompression lock or chamber. The applicant proposes that it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all of the exposed workers during decompression. The

[4] In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

[5] See, *e.g.,* Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine,* 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, ''Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . . , which provides less and less meaningful bubble suppression . . . .'' In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that ''[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control.''

applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

F. Multi-State Variance

As previously stated in this notice, TSJV seeks a permanent variance from several provisions of OSHA's standards regulating work in compressed-air environments for TSJV's tunneling work on the Alexandria RiverRenew Project in Alexandria, Virginia and Washington, DC. The Commonwealth of Virginia has an OSHA-approved State Plan.

Twenty-nine state safety and health plans have been approved by OSHA under section 18 of the OSH Act.[6] Under 29 CFR 1902.8(c), an employer may apply to Federal OSHA for a variance where a state standard is identical to a federal standard addressing the same hazard, and the variance would be applicable to employment or places of employment in more than one state, including at least one state with an approved plan.

TSJV's variance application fits the parameters of 29 CFR 1902.8, and Federal OSHA's action on this application will be deemed prospectively an authoritative interpretation of TSJV's compliance obligations regarding the applicable state standards in the places of employment covered by the application. As part of the process of evaluating this requested permanent variance, OSHA's Directorate of Cooperative and State Programs requested approval from the Virginia State Plan regarding this request. On May 26, 2022, the Virginia State Plan provided notice to OSHA that it will honor OSHA's actions on the variance request (see OSHA–2022–0009–0004).

V. Decision

After reviewing the proposed alternatives, OSHA has determined that the applicant's proposed alternatives on the whole, subject to the conditions in the request and imposed by this permanent variance, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section II of this notice.

In addition, OSHA has determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(e)(5)

The applicant has developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i. The alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i. while engaged in the construction of a subaqueous tunnel using advance shielded mechanical-excavation techniques in conjunction with the TBM. Prior to conducting interventions in the TBM's pressurized working chamber, TSJV halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. 29 CFR 1926.803(f)(1)

The applicant has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.,* staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the five previous permanent variances to IHP JV, Traylor JV, Tully JV, Salini-Impregilo Joint Venture, and Ballard, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.,* the 1992 French Decompression Tables) TSJV proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions imposed by the permanent variance.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard. For example, H.L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).[7] This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events, and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H.L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.[8]

[6] Seven State Plans (Connecticut, Illinois, Maine, Massachusetts, New Jersey, New York, and the Virgin Islands) limit their occupational safety and health authority to state and local employers only. State Plans that exercise their occupational safety and health authority over both public- and private-sector employers are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming.

[7] Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine,* 29(3), pp. 172–188.

[8] Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS,* pp. 1–5 (see Ex. OSHA–2012–0036–0005).

OSHA's experience with the previous five variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provide evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans [9] that either granted variances (Nevada, Oregon and Washington) [10] or promulgated a new standard (California) [11] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, provide additional evidence of the effectiveness of this alternative procedure.

C. 29 CFR 1926.803(g)(1)(iii)

The applicant developed, and proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this preliminary conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of State Plan States, and a review of the literature and other information noted earlier.

D. 29 CFR 1926.803(g)(1)(xvii)

The applicant developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 75 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Based on a review of available evidence, the experience of State Plans that either granted variances (Nevada, Oregon, and Washington) [12] or promulgated a new standard (California) [13] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Pursuant to Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the agency finds that when TSJV complies with the conditions of the following order, the working conditions of the workers are at least as safe and healthful as if it complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, TSJV must: (1) comply with the conditions listed below under ''Conditions Specified for the Permanent Variance'' for the period between the date of this notice and completion of the Alexandria RiverRenew Tunnel Project; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of the application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) completion of the Alexandria RiverRenew Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

VI. Description of the Specified Conditions for the Permanent Variance

The conditions for the variance are set out in the Order at the end of this document. This section provides additional detail regarding the conditions in the Order.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified. Clearly defining the scope of the permanent variance provides TSJV, TSJV's employees, potential future applicants, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the permanent variance applies. To the extent that TSJV exceeds the defined scope of this variance, it will be required to comply with OSHA's standards. This permanent variance applies only to the applicant, TSJV, and only to the remainder of Alexandria RiverRenew Tunnel Project.

Condition B: List of Abbreviations

Condition B defines a number of abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition C: Definitions

The condition defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. OSHA believes that defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition D: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA an HOM specific to the Alexandria RiverRenew Tunnel Project at least six months before using the TBM for tunneling operations. The applicant must also submit, at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or the most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant

[9] Under Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as ''State Plan States'' Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

[10] These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

[11] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

[12] These state variances are available in the docket: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0007 (Oregon), and OSHA–2012–0035–0008 (Washington).

[13] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM enables OSHA to determine whether the safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO–1.2019 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure. The applicant has submitted the HOM and proof of compliance with ASME PVHO–1.2019.

Additionally, the condition includes a series of related hazard prevention and control requirements and methods (*e.g.,* decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition E: Communication

This condition requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication are intended to ensure that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Condition F: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work is intended to ensure that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if the workers believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Condition G: Inspections, Tests, and Accident Prevention

Condition G requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the jobsite for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition H: Compression and Decompression

This condition requires the applicant to consult with the designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical advisor. This proposed provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation has an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Condition I: Recordkeeping

Under OSHA's existing recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore TSJV must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding questions on the form) are:

Q14
- the task performed;
- the composition of the gas mixture (*e.g.,* air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15
- time of symptom onset;
- duration between decompression and onset of symptoms

Q16
- type and duration of symptoms;
- a medical summary of the illness or injury

Q17
- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.[14]

[14] See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (*http://*

Condition J below adds additional reporting responsibilities, beyond those already required by the OSHA standard. The applicant is required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under Condition J, in concert with the information provided under Condition I (using OSHA Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, and 1904.8–.12), enables the applicant and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition J: Notifications

Under the notification condition, the applicant is required, within specified periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations; (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect TSJVs ability to comply with the conditions of the permanent variance; and (6) provide OTPCA and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and, based on this assessment, whether to revise or revoke the conditions of the permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the permanent variance to a successor company. In addition, the condition specifies that the transfer of the permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the permanent variance and expedite the agency's administration and enforcement of the permanent variance. Stipulating that an applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the permanent variance.

VI. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on September 6, 2022, and replacing it with a permanent variance order. Note that there are not any substantive changes in the conditions between the interim order and this final order.

OSHA issues this final order authorizing TSJV to comply with the following conditions instead of complying with the requirements of 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). These conditions are:

A. Scope

The permanent variance applies only when TSJV stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.,* inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Alexandria RiverRenew Tunnel Project, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an TBM;
2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and
3. Performed in compliance with all applicable provisions of 29 CFR part 1926 except for the requirements specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii).
4. This order will remain in effect until one of the following conditions occurs: (1) completion of the Alexandria RiverRenew Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. List of Abbreviations

Abbreviations used throughout this permanent variance includes the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. DMT—Diver Medical Technician
5. TBM—Earth Pressure Balanced Tunnel Boring Machine
6. HOM—Hyperbaric Operations Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

C. Definitions

The following definitions apply to this permanent variance, TSJV's project-

www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and OSHA Recordkeeping Handbook (*http://www.osha.gov/recordkeeping/handbook/index.html*).

specific HOM, and all work carried out under the conditions of this permanent variance.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term ''employee'' has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 pounds per square inch absolute (p.s.i.a)., 1 atmosphere absolute, or 0 p.s.i.g.

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 52.5 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[15]

5. *Decompression illness*—an illness (also called decompression sickness or ''the bends'') caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include, but are not limited to: joint pain (also known as the ''bends'' for agonizing pain or the ''niggles'' for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).[16]

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O_2) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate a tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.[17]

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by TSJV for working in compressed air during the Alexandria RiverRenew Tunnel Project.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man-lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into, or out of, a working chamber.

14. *Medical Advisor*—medical professional experienced in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area. Usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

17. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

18. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g. At sea level the gauge pressure is 0 psig.

19. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[18]

20. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man-lock.

D. Safety and Health Practices

1. TSJV must implement the project-specific HOM submitted to OSHA as part of the application (see OSHA–2022–0009–0003). The HOM provides the minimum requirements regarding expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. TSJV must demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. TSJV must implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. TSJV must ensure that there are no exposures to pressures greater than 52.5 p.s.i.g.

5. TSJV must ensure that air or oxygen is the only breathing gas in the working chamber.

6. TSJV must follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM; specifically, the extracted portions of the 1992 French Decompression tables titled, ''French Regulation Air Standard Tables.''

7. TSJV must equip man-locks used by employees with an air or oxygen delivery system, as specified by the HOM for the project. TSJV is prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

[15] Adapted from 29 CFR 1926.32(f).

[16] See Appendix 10 of ''A Guide to the Work in Compressed-Air Regulations 1996,'' published by the United Kingdom Health and Safety Executive available from NIOSH at *http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf.*

[17] Also see 29 CFR 1910.146(b).

[18] Adapted from 29 CFR 1926.32(m).

9. In hyperbaric work areas, TSJV must maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. TSJV must develop and implement one or more Job Hazard Analysis (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.,* after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk assessment [19] indicates are essential to prevent injury or illness.

11. TSJV must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by the permanent variance (including all procedures required by the HOM approved by OSHA for the project, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. TSJV must ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.

E. Communication

1. Prior to beginning a shift, TSJV must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rock slides, cave-ins, flooding, fires, or explosions.

2. TSJV must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) TSJV must use an independent power supply for powered communication systems, and these systems have to operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) TSJV must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

[19] See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

F. Worker Qualifications and Training

TSJV must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction on hyperbaric conditions, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, and document this instruction. The instruction must include:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (*e.g.,* barotrauma, nitrogen narcosis, and oxygen toxicity);

(d) How to avoid discomfort during compression and decompression;

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (G) of this condition periodically and as necessary (*e.g.,* after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's nearest affected Area Office(s) before the training takes place.

G. Inspections, Tests, and Accident Prevention

1. TSJV must initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the TBM.

2. Remove from service any equipment that constitutes a safety hazard until it corrects the hazardous condition and has the correction approved by a qualified person.

3. TSJV must maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job site for the duration of the job.

H. Compression and Decompression

TSJV must consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

I. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, TSJV must maintain records of:

1. The date, times (*e.g.,* time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

J. Notifications

1. To assist OSHA in administering the conditions specified herein, TSJV must:

(a) Notify the OTPCA and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington of any recordable injury, illness, or fatality (by submitting the completed OSHA Form 301 Injuries and Illness Incident Report) [20] resulting from exposure of an employee to hyperbaric conditions, including those that do not require recompression treatment (*e.g.,* nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness

[20] See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (*http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631*); recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and the OSHA Recordkeeping Handbook (*http://www.osha.gov/recordkeeping/handbook/index.html*).

criteria of 29 CFR 1904. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality; a copy of the incident investigation (OSHA Form 301 Injuries and Illness Incident Report) must be submitted to OSHA within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by OSHA Form 301 Injuries and Illness Incident Report, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification to the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington within 15 working days of the incident that TSJV informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington within 15 working days and in writing, of any change in the compressed-air operations that affects TSJV's ability to comply with the conditions specified herein.

(d) Upon completion of the Alexandria RiverRenew Tunnel Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington.

Note: The evaluation report must contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA Form 301 Injuries and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses, and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the OSHA Area Offices in Norfolk, Virginia and Baltimore/Washington as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

(i) Cease doing business;

(ii) Change the location and address of the main office for managing the tunneling operations specified herein; or

(iii) Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of its application for a permanent variance.

(g) This permanent variance cannot be transferred to a successor company without OSHA approval.

OSHA hereby grants a permanent variance to TSJV to the provisions of 29 CFR 1926.803 outlined in this notice.

VII. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(d), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1905.11.

Signed at Washington, DC, on March 3, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–04882 Filed 3–9–23; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Wage and Hour Division

Agency Information Collection Activities; Comment Request; Information Collections: Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice and request for comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA). 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. Currently, the Wage and Hour Division is soliciting comments concerning its proposal to revise Office of Management and Budget (OMB) approval of the Information Collection: Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act. 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 May 9, 2023.

ADDRESSES: You may submit comments identified by Control Number 1235–0002, 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 OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Robert Waterman, Division of Regulations, Legislation, and Interpretation, Wage and Hour, 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 Migrant and Seasonal Agricultural Worker Protection Act (MSPA) safeguards migrant and seasonal agricultural workers in their interactions with Farm Labor Contractors, Agricultural Employers and Agricultural Associations, and providers

of migrant farm worker housing. See Public Law 97–470. MSPA requires Farm Labor Contractors, Agricultural Employers, and Agricultural Associations, who recruit, solicit, hire, employ, furnish, transport, or house agricultural workers, as well as providers of migrant housing, to meet certain minimum requirements in their dealings with migrant and seasonal agricultural workers. Various sections of the MSPA require respondents (*e.g.,* Farm Labor Contractors, Agricultural Employers, and Agricultural Associations) to disclose terms and conditions in writing to their workers. MSPA sections 201(g) and 301(f) require providing such information in English or, as necessary and reasonable, in a language common to the workers and that the U.S. Department of Labor (Department) make forms available to provide such information. The Department makes optional-use form WH–516, Worker Information—Terms and Conditions of Employment available for these purposes.

MSPA sections 201(d) and 301(c)—29 U.S.C. 1821(d), 1831(c) and regulations 29 CFR 500.80(a), require each Farm Labor Contractor, Agricultural Employer, and Agricultural Association that employs a migrant or seasonal worker to make, keep, and preserve records for 3 years for each such worker concerning the (1) basis on which wages are paid; (2) number of piece work units earned, if paid on a piece work basis; (3) number of hours worked; (4) total pay period earnings; (5) specific sums withheld and the purpose of each sum withheld; (6) net pay. Respondents are also required to provide an itemized written statement of this information to each migrant and seasonal agricultural worker each pay period. See 29 U.S.C. 1821(d), 1831(c), and 29 CFR 500.1–.80(d). Additionally, MSPA sections 201(e) and 301(d) require each Farm Labor Contractor to provide copies of all the records noted above for the migrant and seasonal agricultural workers the contractor has furnished to other Farm Labor Contractors, Agricultural Employers, or Agricultural Associations who use the workers. Respondents must also make and keep certain records. Section 201(c) of the MSPA requires all Farm Labor Contractors, Agricultural Employers, and Agricultural Associations providing housing to a migrant agricultural worker to post in a conspicuous place at the site of the housing, or present to the migrant worker, a written statement of any housing occupancy terms and conditions. See 29 U.S.C. 1821(c); 29 CFR 500.75. In addition, MSPA section 201(g) requires them to provide such information in English, or as necessary and reasonable, in a language common to the workers. See 29 U.S.C. 1821(g). The provision also requires Department make the optional forms available to provide the required disclosures. See 29 U.S.C. 1821(g); 29 CFR 500.1(i)(2). The Department makes optional-use form WH–501, Wage Statement available for this purpose.

MSPA section 201(c)—29 U.S.C. 1821(c) and regulations 29 CFR 500.75(f)–(g), require each Farm Labor Contractor, Agricultural Employer, and Agricultural Association that provides housing for any migrant agricultural worker shall post in a conspicuous place at the site of the housing or present in the form of a written statement to the worker the following information on the terms and conditions of occupancy of such housing, if any: (1) The name and address of the farm labor contractor, agricultural employer or agricultural association providing the housing; (2) The name and address of the individual in charge of the housing; (3) The mailing address and phone number where persons living in the housing facility may be reached; (4) Who may live at the housing facility; (5) The charges to be made for housing; (6) The meals to be provided and the charges to be made for them; (7) The charges for utilities; and (8) Any other charges or conditions of occupancy. The provision also requires that the Department make the optional forms available to provide the required disclosures. See 29 U.S.C. 1821(c); 29 CFR 500.75(g). The Department makes optional-use form WH–521, Housing Terms and Conditions available for this purpose.

II. Review Focus: The Department of Labor is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- 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;
- 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 revision of this information collection in order to ensure effective administration of the Migrant and Seasonal Agricultural Worker Protection Act.

Type of Review: Revision.

Agency: Wage and Hour Division.

Title: Disclosure to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act.

OMB Control Number: 1235–0002.

Affected Public: Business or other for-profit, Not-for-profit institutions, Farms.

Agency Numbers: Forms WH–501 (English and Spanish versions), WH–516 (English, Spanish and Haitian Creole versions), and WH–521.

Total Respondents: 94,729.

Total Annual Responses: 72,606,389.

Estimated Total Burden Hours: 1,228,769.

Estimated Time per Response: Various.

Frequency: On occasion.

Total Burden Cost (capital/startup/operation/maintenance): $2,904,255.

Dated: March 6, 2023.

Amy DeBisschop,

Director, Division of Regulations, Legislation, and Interpretation.

[FR Doc. 2023–04884 Filed 3–9–23; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Oversight hereby gives notice of the scheduling of a videoconference meeting 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: Wednesday, March 15, 2023, from 10:30–11:30 a.m. EDT.

PLACE: This meeting will be held by videoconference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the meeting is: Committee Chair's opening remarks and welcome new members; Approval of prior minutes; Presentations and Discussion of the FY 2021 Merit Review Digest, NSF biennial survey of proposers and Reviewers, and consideration of future formats; the Chief Financial Officer update and presentation; and Committee Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is:

(Chris Blair, *cblair@nsf.gov*), 703/292–7000. Members of the public can observe this meeting through a You Tube livestream. The YouTube link will be available from the NSB meetings web page—*https://www.nsf.gov/nsb/meetings/index.jsp.*

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2023–05063 Filed 3–8–23; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Notice of Intent To Reinstate Information Collection

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to reinstate this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by May 9, 2023 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

Comments: 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; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) 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.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Survey of Science and Engineering Research Facilities.

OMB Control Number: 3145–0101.

Expiration Date of Current Approval: Not applicable.

Type of Request: Intent to seek approval to reinstate an information collection for three years.

Abstract: Established within NSF by the America COMPETES Reauthorization Act of 2010 § 505, codified in the NSF Act of 1950, as amended, NCSES—one of 13 principal federal statistical agencies—serves as a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, and research and development for use by practitioners, researchers, policymakers, and the public.

The Survey of Science and Engineering Research Facilities is a Congressionally mandated (Pub. L. 99–159), biennial census that has been conducted since 1986. The survey collects data on the amount, condition, costs, and funding of the physical facilities used to conduct science and engineering research at U.S. academic institutions. Congress expected that this survey would provide the data necessary to describe the status and needs of science and engineering research facilities and would help formulate appropriate solutions to documented needs. During the FY 2019 and FY 2021 survey cycles, data were collected from a population of approximately 585 research-performing universities. Data are collected through a Web-based interface, although institutions have the option of printing and completing a PDF that can be sent by mail.

Use of the Information: The proposed project will continue the biennial survey for two cycles: FY 2023 and FY 2025. The Survey of Science and Engineering Research Facilities will provide continuity of statistics on the status of scientific and engineering research facilities and capabilities. Statistics on the square footage of research and development (R&D) space available, the condition of R&D space, and the costs for new construction, repairs, and renovation of R&D space at higher education institutions by science and engineering R&D field are produced from the survey. The sources of funding for new construction and repair and renovation projects are also published. The information can be used by Federal policy makers, planners, and budget analysts in making policy decisions, as well as by institutional academic officials, the scientific/engineering establishment, and state agencies and legislatures that fund universities.

Data are published in NCSES's biennial publication series *Survey of Science and Engineering Research Facilities,* available on the web at *http://www.nsf.gov/statistics/srvyfacilities/.*

Expected Respondents: The Facilities Survey is a census of institutions that performed at least $1 million in separately accounted for science and engineering research and development in the previous fiscal year.

In the most recent FY 2021 Facilities Survey, a census of 584 academic institutions was conducted. The sampling frame used for the survey was the FY 2020 Higher Education Research and Development Survey conducted by the National Center for Science and Engineering Statistics.

Estimate of Burden: The Facilities Survey will be sent to approximately 600 academic institutions for both the FY 2023 and FY 2025 data collection cycles. Response to this voluntary survey is typically 97 percent each cycle. The average burden estimate is 19 hours per academic institution based on completion time estimates provided by all survey participants in the FY 2013 survey. The expected estimated burden per survey cycle is 11,400 hours (600 institutions × 19 hours to complete). The total estimated burden is 22,800 for both years combined.

BURDEN ESTIMATE FOR THE FY 2023 AND FY 2025 SURVEYS

Year	Respondents	Average response time (hours)	Total burden (hours)
2023	600	19	11,400

BURDEN ESTIMATE FOR THE FY 2023 AND FY 2025 SURVEYS—Continued

Year	Respondents	Average response time hours	Total burden (hours)
2025	600	19	11,400
Total Burden	1,200		22,800

Dated: March 6, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–04881 Filed 3–9–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of March 13, 20, 27, April 3, 10, 17, 2023. 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 and closed.

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 *Tyesha.Bush@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of March 13, 2023

Friday, March 17, 2023

10 a.m. Affirmation Session (Public Meeting) (Tentative). Susquehanna Nuclear, LLC (Susquehanna Steam Electric Station, Units 1 and 2)—Ruling on Eric Epstein's Petition to Intervene and Request for Hearing (Tentative). (Contact: Wesley Held: 301–287–3591)

Additional Information: The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

There are no meetings scheduled for the week of March 13, 2023.

Week of March 20, 2023—Tentative

There are no meetings scheduled for the week of March 20, 2023.

Week of March 27, 2023—Tentative

Tuesday, March 28, 2023

10 a.m. Briefing on the Annual Threat Environment (Closed Ex. 1)

Thursday, March 30, 2023

9 a.m. Briefing on Nuclear Regulatory Research Program (Public Meeting). (Contact: Nicholas Difrancesco: 301–415–1115)

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 April 3, 2023—Tentative

There are no meetings scheduled for the week of April 3, 2023.

Week of April 10, 2023—Tentative

There are no meetings scheduled for the week of April 10, 2023.

Week of April 17, 2023—Tentative

Thursday, April 20, 2023

9 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Public Meeting). (Contact: Kellee Jamerson: 301–415–7408)

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/.*

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: March 8, 2023.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2023–05104 Filed 3–8–23; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–263; NRC–2023–0031]

Notice of Intent To Conduct Scoping Process and Prepare Environmental Impact Statement; Northern States Power Company—Minnesota; Monticello Nuclear Generating Plant, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Intent to conduct scoping process and prepare environmental impact statement; public scoping meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will conduct a scoping process to gather information necessary to prepare an environmental impact statement (EIS) to evaluate the environmental impacts for the subsequent license renewal (SLR) of the Renewed Facility Operating License No. DPR–22 for Monticello Nuclear Generating Plant, Unit 1 (Monticello). The NRC is seeking public comment on this action and has scheduled a public scoping meeting that will take place in person in Monticello, Minnesota on March 22, 2023, followed by a public scoping webinar meeting at a later date.

DATES: The NRC will hold an in-person public scoping meeting on March 22, 2023, from 6 to 8 p.m. local time. A public scoping webinar will be held at a later date following the in-person public scoping meeting. Submit comments on the scope of the EIS by April 10, 2023. Comments received after

this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. See section IV, ''Public Scoping Meeting,'' of this notice for additional information.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

• *Federal rulemaking website:* Go to *https://regulations.gov* and search for Docket ID NRC–2023–0031. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Email comments to: MonticelloEnvironmental@nrc.gov.*

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jessica Umana, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5207, email: *Jessica.Umana@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0031 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking website:* Go to *https://regulations.gov* and search for Docket ID NRC–2023–0031.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if it is available in ADAMS) is provided the first time that it is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

• *Public Library:* A copy of the SLR application for the Monticello, including the environmental report (ER), is available for public review at the following public library location: Monticello Great River Regional Library, 200 W 6th St., Monticello, MN 55362.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0031 in the subject line of your comment submission in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

By letter dated January 9, 2023 (ADAMS Accession No. ML23009A353), Northern States Power Company, a Minnesota corporation, submitted to the NRC an application for subsequent license renewal of Renewed Facility Operating License No. DPR–22, Unit 1, for an additional 20 years of operation. This submission initiated the NRC's proposed action of determining whether to grant the SLR application. The Monticello unit is a boiling water reactor designed by General Electric and is located in central Minnesota on the banks of the Mississippi River in Sherburne and Wright counties, approximately 38 miles northwest of Minneapolis, MN. The current renewed facility operating license for Unit 1 expires at midnight on September 8, 2030. The SLR application was submitted pursuant to part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants,'' and seeks to extend the renewed facility operating license for Unit 1 to midnight on September 8, 2050. A notice of receipt and availability of the application was published in the **Federal Register** on January 31, 2023 (88 FR 6327).

III. Request for Comment

This notice informs the public of the NRC's intention to conduct environmental scoping and prepare an EIS related to the SLR application for Monticello, and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29, ''Scoping-environmental impact statement and supplement to environmental impact statement.''

The regulations in 36 CFR 800.8, ''Coordination with the National Environmental Policy Act,'' allow agencies to use their National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) (NEPA) process to fulfill the requirements of Section 106 of the National Historic Preservation Act of 1966 (54 U.S.C. 300101, *et seq.*) (NHPA).

Therefore, pursuant to 36 CFR 800.8(c), the NRC intends to use its process and documentation required for the preparation of the EIS on the proposed action to comply with Section 106 of the NHPA in lieu of the procedures set forth at 36 CFR 800.3 through 800.6.

In accordance with 10 CFR 51.53(c) and 10 CFR 54.23, Monticello submitted an ER as part of the SLR application. The ER was prepared pursuant to 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' and is available in ADAMS under Accession No. ML23009A356. The ER will also be available for viewing at *https://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-*

renewal.html. In addition, the SLR application, including the ER, is available for public review at the Monticello Great River Regional Library, 200 W 6th St, Monticello, MN 55362.

The NRC intends to gather the information necessary to prepare a plant-specific supplement to NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants'' (ADAMS Package Accession No. ML13107A023) (GEIS), related to the SLR application for Monticello. The NRC is required by 10 CFR 51.95 to prepare a plant-specific supplement to the GEIS in connection with the renewal of an operating license. This notice is being published in accordance with NEPA and the NRC's regulations at 10 CFR part 51.

The supplement to the GEIS will evaluate the environmental impacts of subsequent license renewal for Monticello and reasonable alternatives thereto. Possible alternatives to the proposed action include the no action alternative and reasonable alternative energy sources.

As part of its environmental review, the NRC will first conduct a scoping process for the plant-specific supplement to the GEIS and, as soon as practicable thereafter, will prepare a draft supplement to the GEIS for public comment. Participation in this scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the supplement to the GEIS will be used to accomplish the following:

a. Define the proposed action that is to be the subject of the supplement to the GEIS;

b. Determine the scope of the supplement to the GEIS and identify the significant issues to be analyzed in depth;

c. Identify and eliminate from detailed study those issues that are peripheral or are not significant or that have been covered by prior environmental review;

d. Identify any environmental assessments and other ElSs that are being or will be prepared that are related to, but are not part of, the scope of the supplement to the GEIS under consideration;

e. Identify other environmental review and consultation requirements related to the proposed action;

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the NRC's tentative planning and decision-making schedule;

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the supplement to the GEIS to the NRC and any cooperating agencies; and

h. Describe how the supplement to the GEIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in scoping:

a. The applicant, Northern States Power Company;

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards;

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards;

d. Any affected Indian Tribe;

e. Any person who requests or has requested an opportunity to participate in the scoping process; and

f. Any person who has petitioned or intends to petition for leave to intervene under 10 CFR 2.309.

IV. Public Scoping Meeting

In accordance with 10 CFR 51.26(b), the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to the proposed action and to determine the scope of issues to be addressed in the EIS.

The NRC is announcing that it will hold an in-person public scoping meeting for the Monticello SLR supplement to the GEIS; a virtual public scoping meeting is to follow at a later date. A court reporter will transcribe all comments received during the public scoping meeting. To be considered, comments must be provided either at a transcribed public meeting or in writing, as discussed in the **ADDRESSES** section of this notice. The in-person public scoping meeting information is as follows.

Meeting	Date	Time	Location
Public EIS Scoping	Wednesday, 03/22/2023 ...	6 p.m.–8 p.m., as necessary.	Monticello Community Center, 505 Walnut St., Monticello, MN 55362.

Persons interested in attending this meeting should monitor the NRC's Public Meeting Schedule website at *https://www.nrc.gov/pmns/mtg* for additional information and the agenda for the meeting. Please contact Ms. Jessica Umana no later than March 16, 2023, if accommodations or special equipment is needed to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated.

The public scoping meeting will include: (1) an overview by the NRC staff of the environmental and safety review processes, the proposed scope of the supplement to the GEIS, and the proposed review schedule; and (2) the opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on environmental issues or the proposed scope of the Monticello SLR supplement to the GEIS.

Participation in the scoping process for the Monticello SLR supplement to the GEIS does not entitle participants to become parties to the proceeding to which the supplement to the GEIS relates. Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting.

Dated: March 7, 2023.

For the Nuclear Regulatory Commission.

Theodore B. Smith,

Chief, Environmental Review License Renewal Branch, Division of Rulemaking, Environment, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–04963 Filed 3–9–23; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Representative Payee Application/ Information Necessary for a Competency Determination

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction of 1995, Retirement Services, Office of Personnel Management (OPM) is offering the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), RI 20–7 *[Representative Payee*

Application] and RI 30–3 *[Information for a Competency Determination].*

DATES: Comments are encouraged and will be accepted until April 10, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *http://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: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or may be obtained by sending an email to *Cyrus.Benson@opm.gov* or by fax to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (44 U.S.C. 35) as amended by the Clinger-Cohen Act of 1996, Public Law 104–106, 110 Stat. 642 (40 U.S.C. 1401 *et seq.*), OPM is soliciting comments for this collection (OMB No. 3206–0140). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Form RI 20–7 is used by the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS) to collect information from persons who apply to be fiduciaries for annuitants or survivor annuitants who appear to be incapable of handling their own funds or for minor children. RI 30–3 is an enclosure to RI 20–7 and is needed for adult annuitants who are alleged to be incompetent. RI 30–3 collects medical information regarding the annuitant's competency for OPM's use in evaluating the annuitant's condition.

Analysis

Agency: Retirement Services, Office of Personnel Management.

Title: Representative Payee Application/Information Necessary for a Competency Determination.

OMB Number: 3206–0140.

Frequency: On occasion.

Affected Public: Individuals or Organizations.

Number of Respondents: 12,480 [RI 20–7] and 250 [RI 30–3].

Estimated Time per Respondent: 30 minutes [RI 20–7] and 1 hour [RI 30–3].

Total Burden Hours: 6,240 [RI 20–7] and 250 [RI 30–3].

Office of Personnel Management.

Kellie Cosgrove Riley,

Director, Office of Privacy and Information Management.

[FR Doc. 2023–04940 Filed 3–9–23; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97048; File No. SR–NYSE–2023–15]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 313

March 6, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 27, 2023, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 313 to eliminate text reflecting outdated requirements. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 313 to delete the current text of Supplementary Material .22 and designate Rule 313.22 as ''Reserved.''

Rule 313 sets forth certain corporate, limited liability company, or partnership documents that each member organization must submit to the Exchange to enter into and continue in NYSE membership. The Rule also sets forth certain restrictions on capital withdrawals and distributions applicable to member corporations and partnerships.

Rule 313.22 currently provides that the certificate of incorporation of a member corporation must contain provisions authorizing the corporation to redeem or convert outstanding shares of voting stock to a fixed income security when such shares are owned by any person required to be approved by the Board of Directors of the Exchange as a member or approved person and such person fails or ceases to be so approved, as may be necessary to reduce such party's ownership of voting stock in the member corporation below the level that would enable such party to exercise controlling influence over the management or policies of such member corporation.

Rule 313.22 also provides that, if the certificate of incorporation of a member corporation subject to Rule 325 provides that a stockholder may compel the redemption of his stock, such certificate must provide that, unless such stockholder has prior written approval of the Exchange, the redemption may

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

only be effected on a date not less than six months after receipt by the member corporation of a written request for redemption, given no sooner than six months after the date of the original issuance of such shares (or any predecessor shares). Rule 313.22 also requires a member corporation to promptly notify the Exchange of the receipt of any request for redemption of any stock or if any redemption is not made because prohibited under the provisions of Rule 15c3–1.[3]

Finally, Rule 313.22 provides that each stock certificate of a member corporation must state, on its face, the restrictions set forth in Rule 15c3–1(e) relating to the redemption of stock or a full summary thereof.

Proposed Rule Change

The Exchange proposes to delete the text of Rule 313.22 and designate Rule 313.22 as ''Reserved.''

The Exchange believes that Rule 313.22, which was adopted in 1970 and last amended in 1976 to incorporate references to then newly adopted Rule 15c3–1,[4] requiring a member corporation's certificate of incorporation to contain specific provisions relating to the redemption and conversion of stock and requiring a member corporation's stock certificate to include the restrictions set forth in Rule 15c3–1(e) relating to the redemption of stock no longer serves a regulatory, business or investor protection purpose and in fact poses an unnecessary obstacle for prospective applicants for Exchange membership. Specifically, the Exchange believes that the provisions of Rule 313.22 are duplicative of the requirements of Rule 15c3–1, as well as other Exchange and Financial Industry Regulatory Authority, Inc. (''FINRA'') rules adopted subsequent to the implementation of Rule 313.22. The Exchange notes that the proposed change relates only to Rule 313.22's requirements concerning the contents of a member organization's certificate of incorporation or stock certificate and would not otherwise impact a member organization's continuing obligation to comply with the net capital requirements of Rule 15c3–1, including pursuant to NYSE Rule 4110 and, for the large number of member organizations that are also members of FINRA, FINRA Rule 4110. Both NYSE Rule 4110 and FINRA Rule 4110 require, among other things, that a member organization must suspend business operations during any period in which it is not in compliance with applicable net capital requirements set forth in Rule 15c3–1 and that no equity capital of a member organization may be withdrawn for a period of one year from the date such equity capital is contributed.[5]

The Exchange believes that the elimination of the requirements set forth in current Rule 313.22 would simplify the membership application process without impacting the Exchange's ability to ensure that member organizations are qualified for Exchange membership and would be held to the requirements of Exchange rules. Prospective member organizations would continue to be subject to the membership application process, which calls for applicants to submit materials including organizational documents, financial statements, and records relating to the organization's designated supervisors and principals.[6] Approved member organizations are bound to abide by Exchange rules, and the Exchange would continue to have the authority to enforce member organizations' obligations under Exchange rules (including compliance with relevant net capital requirements pursuant to Rule 15c3–1, as applicable).[7]

The Exchange also believes that the requirements of Rule 313.22, to the extent they necessitate modifications to a member corporation's certificate of incorporation or stock certificate, may be burdensome to prospective member organizations given the potential difficulty of amending such documents and could deter organizations from seeking Exchange membership. The Exchange thus believes that eliminating the requirements of Rule 313.22 could make the membership application process more accessible to prospective member organizations, thereby encouraging additional corporations to consider and apply for Exchange membership.

Finally, Rule 313.22 currently includes a provision referring to member corporations subject to Rule 325, which rule was designated as ''Reserved'' in 2010.[8] Accordingly, the Exchange believes that the portion of Rule 313.22 setting forth requirements relating to corporations subject to Rule 325 likewise no longer has application.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

The Exchange believes that eliminating the requirements of Rule 313.22 with respect to member corporations would remove impediments to and perfect the mechanism of a free and open market and a national market system by simplifying the application process for prospective member organizations and in turn encouraging organizations to apply for Exchange membership. The Exchange believes that the requirements of Rule 313.22 do not currently serve a regulatory or business purpose and do not further investor protection interests, particularly since the deletion of the requirements in Rule 313.22 would not impact the Exchange's ability to make informed decisions with respect to applicants for Exchange membership or to require member organizations to abide by Exchange rules, including rules relating to their net capital obligations pursuant to Rule 15c3–1. The Exchange further believes that the issues that may have been contemplated when Rule 313.22 was adopted (such as ensuring that a member organization's controlling persons are qualified and that member organizations comply with the relevant provisions of Rule 15c3–1) are adequately addressed by both the

[3] *See* 17 CFR 240.15c3–1.

[4] *See* SR–NYSE–75–11. Prior to the change, proprietors had been able to withdraw all of their capital even where such action would result in a capital ratio or minimum dollar capital in violation of the net capital rule.

[5] *See* NYSE Rule 4110 (Capital Compliance); FINRA Rule 4110 (Capital Compliance), available at: *https://www.finra.org/rules-guidance/rulebooks/finra-rules/4110.* The Exchange adopted Rule 4110 in 2010 to harmonize its rules with FINRA Rule 4110. *See* Securities Exchange Act Release No. 61557 (February 22, 2010), 75 FR 9472 (March 2, 2010) (SR–NYSE–2010–10) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by New York Stock Exchange LLC Changing Certain NYSE Rules and Rule Interpretations To Correspond With Rule Changes Filed by the Financial Industry Regulatory Authority, Inc.).

[6] The NYSE membership application is available at: *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Application_for_Membership.pdf.*

[7] The Exchange notes that the proposed change would likewise have no impact on FINRA's authority to enforce its rules with respect to member organizations that are also FINRA members.

[8] *See* Securities Exchange Act Release No. 61557 (February 22, 2010), 75 FR 9472 (March 2, 2010) (SR–NYSE–2010–10) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by New York Stock Exchange LLC Changing Certain NYSE Rules and Rule Interpretations To Correspond With Rule Changes Filed by the Financial Industry Regulatory Authority, Inc.).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

application review process and the processes in place for the oversight of member organizations' compliance with Exchange rules.

The Exchange also believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and is designed to protect investors and the public interest because it would improve the efficiency of the membership application process and the clarity of the Exchange's rules by removing the outdated and unnecessarily burdensome requirements that a member corporation's certificate of incorporation and stock certificate contain specific language relating to the redemption. The Exchange also notes that the proposed change to no longer require specific language referencing Rule 15c3–1 in the certificate of incorporation and stock certificate would not impact a member organization's obligation to comply with the relevant net capital requirements of Rule 15c3–1, including pursuant to NYSE Rule 4110 and FINRA Rule 4110, as applicable. The Exchange further believes that broadening the prospective Exchange membership pool by eliminating requirements that no longer serve regulatory or business purposes and do not offer a necessary investor protection would benefit investors and the public interest by facilitating increased market participation and depth at the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change could promote competition by removing an outdated requirement applicable to prospective member organizations that are corporations. The Exchange believes that deleting the requirements set forth in Rule 313.22 (particularly those calling for modification of a corporation's certificate of incorporation and/or stock certificate) could result in less burdensome and more efficient standards for prospective member organizations to meet, thereby encouraging additional corporations to consider pursuing Exchange membership. Expanding the prospective Exchange membership pool by eliminating a requirement that no longer appears to serve a business, regulatory, or other purpose could promote competition by increasing market participation and depth at the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2023–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2023–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2023–15 and should be submitted on or before March 31, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–04876 Filed 3–9–23; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34846; 812–15424]

JPMorgan Private Markets Fund, et al.

March 6, 2023.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose early withdrawal charges and asset-based distribution and/or service fees with respect to certain classes.

APPLICANTS: JPMorgan Private Markets Fund, J.P. Morgan Investment Management Inc. and J.P. Morgan Institutional Investments Inc.

FILING DATE: The application was filed on January 19, 2023.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on March 31, 2023, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: Carmine Lekstutis, *carmine.lekstutis@jpmorgan.com* and Andrea Santoriello, *andrea.m.santoriello@jpmorgan.com,* JPMorgan Private Markets Fund; Rajib Chanda, Esq., *Rajib.chanda@stblaw.com* and Ryan P. *Brizek@stblaw.com,* Simpson Thacher & Bartlett LLP.

FOR FURTHER INFORMATION CONTACT: Trace W. Rakestraw, Senior Special Counsel, at (202) 551–6825 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and condition, please refer to Applicants' application, dated January 19, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–04866 Filed 3–9–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34848; File No. 812–15437]

Confluent, Inc.

March 6, 2023.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under Section 3(b)(2) of the Investment Company Act of 1940 (''Act'').

APPLICANT: Confluent, Inc.

SUMMARY OF APPLICATION: Applicant seeks an order under Section 3(b)(2) of the Act declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Applicant states that it is in the business of providing to its customers a data infrastructure platform focused on developing and supporting technology designed to enable real-time data, from multiple sources, to constantly stream across an organization.

FILING DATES: The application was filed on February 13, 2023 and amended on March 2, 2023.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request, by email if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on March 31, 2023, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicant: Steffan Tomlinson, Chief Financial Officer, and Melanie Vinson, Chief Legal Officer, Confluent Inc., at *legal@confluent.io;* Amy Caiazza, at *acaiazza@wsgr.com.*

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. For Applicant's representations, legal analysis, and conditions, please refer to Applicant's first amended and restated application, dated March 2, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

Applicant's Representations

1. Applicant states that it is a Delaware corporation formed in 2014 that, directly and through its wholly-owned subsidiaries,[1] is engaged in the

[1] Applicant states that these subsidiaries conduct businesses that are integrally related to the Applicant's business, such as sales and marketing or research and development (''R&D'') activities in their respective jurisdictions.

business of providing to its customers a data infrastructure platform focused on developing and supporting technology designed to enable real-time data, from multiple sources, to constantly stream across an organization. Applicant also states that it offers professional services and educational services in support of its products.

2. Applicant states that its business is highly capital intensive, requires R&D of new technologies, and does not involve the Applicant acquiring or retaining significant ''hard'' operating assets. Applicant states that it maintains significant cash reserves that it seeks to invest for purposes of conserving capital and providing liquidity until the funds are used in its data infrastructure business. As described more fully in the application, Applicant states that it requires significant liquid capital primarily to: (i) advance the commercialization of its products, (ii) make other capital expenditures in keeping with the growth of the Company's operating business, and (iii) fund R&D for new products and services.

3. Applicant states that it has financed operations primarily through offerings of equity and debt securities, but ultimately seeks to generate cash from its operations to support its business. Applicant states that it seeks to preserve capital and maintain liquidity, pending the use of such capital for its business operations, by investing in ''Capital Preservation Instruments''.[2] Applicant states that it may in the future make strategic investments in ''other investments'' consistent with Rule 3a–8. Applicant states that such securities will not be acquired for speculative purposes.

Applicant's Legal Analysis

1. Applicant seeks an order under Section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore is not an investment company as defined in the Act.

2. Section 3(a)(1)(A) of the Act defines the term ''investment company'' to include an issuer that is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities. Section 3(a)(1)(C) of the Act further defines an investment company as an issuer that is engaged or proposes to engage in the business of investing, reinvesting, owning, holding or trading in securities, and owns or proposes to acquire investment securities having a value in excess of 40% of the value of the issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis. Section 3(a)(2) of the Act defines ''investment securities'' to include all securities except Government securities, securities issued by employees' securities companies, and securities issued by majority-owned subsidiaries of the owner which (a) are not investment companies, and (b) are not relying on the exclusions from the definition of investment company in Section 3(c)(1) or Section 3(c)(7) of the Act. Applicant states that it has never been, is not now, and does not propose to be, primarily engaged in the business of investing, reinvesting, owning, holding, or trading in securities. Applicant states, however, that during fiscal years 2019 and 2020 it held investment securities that exceeded 40% of its total assets on an unconsolidated basis (exclusive of government securities and cash items). Applicant states that during this time period it may have met the definition of ''investment company'' pursuant to Section 3(a)(1)(C) of the Act. Applicant states that it has more recently limited its holdings of investment securities to avoid meeting Section 3(a)(1)(C) but states that doing so on a continuous basis may hinder its business over the long term.

3. Rule 3a–8 under the Act provides an exclusion from the definition of investment company if, among other factors, a company's R&D expenses are a substantial percentage of its total expenses for the last four fiscal quarters combined. While Applicant believes that it complies with the conditions of Rule 3a–8, Applicant states that it is concerned that its R&D expenses, while substantial in absolute terms, may not always be considered substantial as a ratio of overall expenses. Although Applicant states that it anticipates R&D expenses to increase in absolute terms, such expenses are not anticipated to increase proportionately with Applicant's overall expenses, particularly given increases in expenses related to sales and marketing, the administration of a rapidly expanding employee base, and other administrative expenses. Applicant states that its R&D expenses as a percentage of total expenses was 22.26% for the twelve months ended December 31, 2021, and Applicant expects the percentage relative to total expenses to decrease over time.

4. Section 3(b)(2) of the Act provides that, notwithstanding Section 3(a)(1)(C) of the Act, the Commission may issue an order declaring an issuer to be primarily engaged in a business other than that of investing, reinvesting, owning, holding, or trading in securities directly, through majority-owned subsidiaries, or controlled companies conducting similar types of businesses. Applicant requests an order under Section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore is not an investment company as defined in the Act.

5. In determining whether an issuer is ''primarily engaged'' in a non-investment company business under Section 3(b)(2) of the Act, the Commission considers the following factors: (a) the company's historical development, (b) its public representations of policy, (c) the activities of its officers and directors, (d) the nature of its present assets, and (e) the sources of its present income.[3]

6. Applicant submits that it satisfies the criteria for issuance of an order under Section 3(b)(2) of the Act because Applicant is primarily engaged in the business of providing data infrastructure services, and is not in the business of investing, reinvesting, owning, holding or trading in securities.

a. *Historical Development.* Applicant states that, since its inception in 2014, Applicant has operated in the software and technology sector to develop comprehensive, scalable data infrastructure services for business use. Applicant states that in March 2021, the number of its customers surpassed 2,500.

b. *Public Representations of Policy.* Applicant states that it has consistently represented that it is engaged in the business of providing data infrastructure services. Applicant further states that it has never held and does not now hold itself out as an investment company within the meaning of the Act or as engaging in the business of investing, reinvesting, owning, holding or trading in securities. Applicant explains that in its annual reports, prospectuses, Commission filings, press releases,

[2] As used in Applicant's application, Capital Preservation Instruments refer collectively to any cash items and securities that are held for the purpose of conserving the Applicant's capital and liquidity until they are used by the Applicant to support its business (as such business is described in Applicant's application). Such holdings are liquid (*i.e.,* can be readily sold), earn competitive market returns and present a low level of credit risk, including short-term investment grade securities, Government securities (as defined in Section 2(a)(16) of the Act), securities of money market funds registered under the Act, and other cash items; but excluding investments in equity or speculative instruments.

[3] *Tonopah Mining Company of Nevada,* 26 SEC 426, 427 (1947).

marketing materials, and on its investor website, Applicant's public representations consistently state its mission of pioneering a fundamentally new category of data infrastructure focused on data in motion. Applicant submits that its public representations make clear that shareholders invest in the Applicant's securities with the expectation of realizing gains from Applicant's development and sale of data infrastructure services, and not from returns on an investment portfolio. Applicant states that its only public representations regarding its investment securities are those required to be disclosed in public filings with the Commission.

c. *Activities of Officers and Directors.* Applicant represents that its officers and directors spend substantially all of their time managing the Applicant's data infrastructure services business. Applicant states that its cash management activities are managed internally by its Chief Financial Officer and externally by three investment managers, whose activities are supervised by the Chief Financial Officer. In addition, of the Applicant's approximately 2,601 employees (as of September 30, 2022), Applicant states that only two employees spend time on matters relating to the management of its Capital Preservation Instruments. Applicant states that none of its officers, directors, or employees devote or proposes to devote more than 1% of his or her time, if even that, to management of Capital Preservation Instruments on behalf of the Applicant.

d. *Nature of Assets.* Applicant states that, as of September 30, 2022, Applicant's investment securities constituted approximately 32% its total assets (excluding Government securities and cash items) on an unconsolidated basis.[4] Furthermore, Applicant states that 100% of its investment securities consist of Capital Preservation Instruments. Applicant uses its Capital Preservation Instruments to finance its continued operations. Applicant states that it needs the ability to invest more than 40% of the total value of its assets (exclusive of Government securities and cash items) on an unconsolidated basis in Capital Preservation Instruments to ensure that funds are managed and available to accommodate future growth of the business and general corporate purposes. In addition, Applicant states that it may in the future make strategic investments in ''other investments'' consistent with Rule 3a–8. Applicant states, however, that no more than 10% of its total assets (exclusive of Government securities and cash items, including securities of money market funds registered under the Act) will consist of investment securities other than Capital Preservation Instruments.[5]

e. *Sources of Income and Revenue.* Applicant represents that since its inception it has carried net operating losses. Applicant states that it does, however, derive income from its investment securities. Applicant states that a review of its current source of revenues provides a more accurate review of its operating company status, particularly given the upward trend in recognizing substantially increased revenues due to sales of new subscriptions. Applicant states that it derives substantially all of its revenue from subscriptions and, to a lesser extent, services. Applicant states that its revenues for the years ended December 31, 2020 and 2021 were $233.6 million and $387.5 million respectively, on an unconsolidated basis. By contrast, Applicant states that it earned $0.8 million in net investment income in 2021 and $2.8 million in 2020. Applicant states that all such income was derived from Capital Preservation Instruments. Applicant states that if net investment income were compared to its revenue, it would be equal to approximately 0.2% of revenue for the fiscal year ended December 31, 2021 and to approximately 1.2% of revenue for the fiscal year ended December 31, 2020.

For the fiscal nine months ended September 30, 2022, Applicant earned $9.6 million of net investment income, representing approximately 2.3% of revenue for that time period. Applicant explains that the increase in net investment income is due to the deployment into Capital Preservation Instruments of the proceeds of its June 2021 initial public offering and December 2021 convertible debt issuance and the increase in interest rates in the fixed income markets.

7. Applicant asserts that its historical development, its public representations of policy, the activities of its officers and directors, the nature of its assets and its sources of income and revenue, as discussed in the application, demonstrate that it is engaged primarily in a business other than that of investing, reinvesting, owning, holding or trading securities. Applicant thus asserts that it satisfies the criteria for issuing an order under Section 3(b)(2) of the Act.

Applicant's Conditions

Applicant agrees that any order granted pursuant to the application will be subject to the following conditions:

1. Applicant will continue to use its accumulated cash and securities to support its primary business (as such business is described in Applicant's application);

2. Applicant will refrain from investing or trading in securities for speculative purposes; and

3. No more than 10% of Applicant's total assets will consist of investment securities other than Capital Preservation Instruments (as such capitalized term is described in Applicant's application). For purposes of this condition, total assets excludes cash items (including securities issued by money market funds registered under the Act) and Government securities (as defined in Section 2(a)(16) of the Act). This percentage is to be determined on an unconsolidated basis, except that Applicant should consolidate its financial statements with the financial statements of any wholly-owned subsidiaries.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–04867 Filed 3–9–23; 8:45 am]

BILLING CODE 8011–01–P

[4] Applicant states that none of its subsidiaries hold any investment securities.

[5] Applicant states that it intends to calculate this percentage by consolidating its financial statement with the financial statements of its wholly-owned subsidiaries (but not with any majority-owned subsidiary that may be acquired in the future).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17800 and #17801; OKLAHOMA Disaster Number OK–00165]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Muscogee (Creek) Nation

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Muscogee (Creek) Nation (FEMA–4690–DR), dated 03/03/2023.

Incident: Severe Winter Storm.

Incident Period: 12/21/2022 through 12/25/2022.

DATES: Issued on 03/03/2023.

Physical Loan Application Deadline Date: 05/02/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 12/04/2023.

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 Recovery & Resilience, 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 03/03/2023, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Muscogee (Creek) Nation

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 17800 B and for economic injury is 17801 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2023–04915 Filed 3–9–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17798 and #17799; Louisiana Disaster Number LA–00124]

Administrative Declaration of a Disaster for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Louisiana dated 03/06/2023.

Incident: Severe Storms and a Tornado.

Incident Period: 02/08/2023.

DATES: Issued on 03/06/2023.

Physical Loan Application Deadline Date: 05/05/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 12/06/2023.

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 Recovery & Resilience, 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 Parishes: Tangipahoa.

Contiguous Parishes/Counties:

Louisiana: Jefferson, Livingston, Saint Charles, Saint Helena, Saint Tammany, St John the Baptist, Washington.

Mississippi: Amite, Pike.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.750
Homeowners without Credit Available Elsewhere	2.375
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 17798 C and for economic injury is 17799 0.

The States which received an EIDL Declaration # are Louisiana, Mississippi.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–04933 Filed 3–9–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17802 and #17803; CALIFORNIA Disaster Number CA–00373]

Administrative Declaration of a Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of CALIFORNIA dated 03/07/2023.

Incident: Severe Winter Storms, Flooding, Landslides and Mudslides.

Incident Period: 12/27/2022 through 01/31/2023.

DATES: Issued on 03/07/2023.

Physical Loan Application Deadline Date: 05/08/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 12/07/2023.

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 Recovery & Resilience, 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: San Francisco.

Contiguous Counties:

California: Alameda, Marin, San Mateo.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.625
Homeowners without Credit Available Elsewhere	2.313
Businesses with Credit Available Elsewhere	6.610
Businesses without Credit Available Elsewhere	3.305
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.305

	Percent
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 17802 6 and for economic injury is 17803 0.

The State which received an EIDL Declaration # is California.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–04929 Filed 3–9–23; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2022–0057]

Privacy Act of 1974; Matching Program

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a new matching program with the Railroad Retirement Board (RRB). Under this matching program, RRB, as the source agency, will disclose RRB annuity payment data to SSA, the recipient agency. SSA will use the information to verify Supplemental Security Income (SSI) and Special Veterans Benefits (SVB) eligibility and benefit payment amounts. SSA will also record the railroad annuity amounts RRB paid to SSI and SVB recipients in the Supplemental Security Income Record (SSR).

DATES: The deadline to submit comments on the proposed matching program is April 10, 2023. The matching program will be applicable on September 2, 2023, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will be in effect for a period of 18 months.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2022–0057 so that we may associate your comments with the correct regulation. CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *https://www.regulations.gov.* Use the *Search* function to find docket number SSA–2022–0057 and then submit your comments. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each submission manually. It may take up to a week for your comments to be viewable.

2. *Fax:* Fax comments to (833) 410–1631.

3. *Mail:* Matthew Ramsey, Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, G–401 WHR, 6401 Security Boulevard, Baltimore, MD 21235–6401, or emailing *Matthew.Ramsey@ssa.gov.* Comments are also available for public viewing on the Federal eRulemaking portal at *https://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Interested parties may submit general questions about the matching program to Cynthia Scott, Division Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, G–401 WHR, 6401 Security Boulevard, Baltimore, MD 21235–6401, at telephone: (410) 966–1943, or send an email to *Cynthia.Scott@ssa.gov.*

SUPPLEMENTARY INFORMATION: None.

Matthew Ramsey,

Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

Participating Agencies: SSA and RRB.

Authority for Conducting the Matching Program: This matching agreement is executed in compliance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, and the regulations and guidance promulgated thereunder.

Legal authority for the disclosure under this agreement for the SSI portion are sections 1631(e)(1)(A) and (B) and 1631(f) of the Social Security Act (Act) (42 U.S.C. 1383(e)(1)(A) and (B) and 1383(f)). The legal authority for the disclosure under this agreement for the SVB portion is section 806(b) of the Act (42 U.S.C. 1006(b)).

Purpose(s): This matching agreement sets forth the terms, safeguards, and procedures under which RRB, as the source agency, will disclose RRB annuity payment data to SSA, the recipient agency. SSA will use the information to verify SSI and SVB eligibility and benefit payment amounts. SSA will also record the railroad annuity amounts RRB paid to SSI and SVB recipients in the SSR.

Categories of Individuals: The individuals whose information is involved in this matching program are applicants for and recipients of SSI payments and SVB benefits.

Categories of Records: The electronic data file provided by RRB will contain approximately 560,000 records. The file will adhere to the characteristics and format shown in attachment B. The SSR has about 10.4 million records. SSA will match the Social Security number, name, date of birth, and RRB claim number on the RRB file and the SSR. SSA and RRB will conduct this match monthly.

System(s) of Records: RRB will provide SSA with an electronic data file containing annuity payment data from RRB's system of records, RRB–22 Railroad Retirement, Survivor, and Pensioner Benefits System, last published on May 15, 2015 (80 FR 28018). SSA will match RRB's data with data maintained in the SSR, Supplemental Security Income Record and Special Veterans Benefits, 60–0103, last fully published at 71 FR. 1830 on January 11, 2006 and updated on December 10, 2007 (72 FR 69723), July 3, 2018 (83 FR 31250–31251), and November 1, 2018 (83 FR 54969). SVB data also resides on the SSR.

[FR Doc. 2023–04948 Filed 3–9–23; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 12002]

SPOG Virtual Public Meeting on Conducting Anti-Trafficking Work Using a Racial Equity Lens

ACTION: Notice of public meeting.

SUMMARY: The Department of State, on behalf of the interagency Senior Policy Operating Group (SPOG), is hosting a virtual public meeting to hear input about how it can conduct its anti-trafficking work using a racial justice and equity lens and to assist the SPOG and SPOG agencies implementation of *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* and *Further*

Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. This public meeting is part of the SPOG's ongoing efforts to engage and collaborate with diverse communities and develop an implementation plan for integrating racial equity into U.S. government anti-trafficking efforts and is meant to complement the SPOG's prior request for written information (87 FR 7231) to provide members of the public with another way to share feedback with the U.S. government. The implementation plan will highlight the importance of an intersectional approach, as racism often compounds with other forms of discrimination to affect individuals' vulnerability to human trafficking. Additionally, it will complement agencies' individual work to implement *Diversity, Equity, Inclusion and Accessibility in the Federal Workforce* by sharing information and practices for increasing diversity in the federal workforce as an integral way to strengthen agencies' anti-trafficking work.

DATES: The SPOG will hold a web-based open public meeting on May 3, 2023, from 1:30 p.m. to 3 p.m. EDT. To attend the public meeting, you must register by April 23, 2023, at 11:59 p.m. EDT.

ADDRESSES: The meeting will be accessible via webcast. To register, go to *www.eventbrite.com/e/public-meeting-on-anti-trafficking-work-using-a-racial-equity-lens-tickets-560732535107.* Registrants will receive the webcast information on May 1, 2023.

FOR FURTHER INFORMATION CONTACT: Jennifer Ho, (202) 453–8473, *TIPOutreach@state.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Department of State, on behalf of the SPOG, is hosting a public meeting to seek input, information, and recommendations from a broad array of stakeholders in the public, private, advocacy, not-for-profit, and philanthropic sectors, including state, local, tribal, and territorial areas, on available methods, approaches, and tools to apply a racial equity lens to federal government anti-trafficking efforts. For more information on the SPOG and on definitions for terms used in this Notice, please refer to the Supplementary Information on this page: *www.state.gov/request-for-information-on-conducting-anti-trafficking-work-using-a-racial-equity-lens.*

The Department welcomes public input that the SPOG can factor into decisions around what specific action items and performance metrics it should include in its implementation plan for integrating a racial equity lens into its anti-trafficking work. This public meeting will begin with brief opening remarks from Department officials. All stakeholders and interested members of the public are welcome to register to provide oral comments; however, based on the meeting duration or topic area constraints, the Department may not be able to allocate time for all registered attendees to provide oral comments during the meeting.

The SPOG is interested in all comments but requests input particularly on any of the following questions for which the stakeholder has direct personal or professional experience:

1. What does racial equity mean in the context of human trafficking? What does a racially equitable anti-trafficking framework look like, particularly for law enforcement and prosecution responses, victim assistance efforts, and prevention strategies? Are there specific considerations for responding to sex trafficking and to labor trafficking?

2. Please describe any racial injustice, inequity, or unfairness you have observed or experienced that resulted from a federal anti-trafficking activity (please specify the relevant policy, practice, or program). Do you have recommendations for how this should be corrected?

3. How have federal anti-trafficking policies, programs, and systems created barriers to advancing racial equity, and how might the executive branch address and help reduce these barriers?

4. What promising approaches or efforts have been successful in embedding a racial equity lens in anti-trafficking work? What examples and/or data are available to support this?

5. What can SPOG agencies do individually or collectively to advance racial equity and integrate it into federal anti-trafficking work domestically and internationally—particularly in the areas of investigation and prosecution, victim services (commenters may specify specific populations, such as people of color, people who are limited English proficient, people with disabilities, noncitizens, LGBTQI+ persons, etc.), grantmaking, public procurement, supply chains, public awareness and outreach, research and data collection, and any other area the submitter feels is important to note?

6. What tools, approaches, or lessons have been applied in other countries or in U.S. state, territorial, tribal, and local jurisdictions to address the intersection between racial, ethnic, linguistic, or cultural discrimination and human trafficking? Could these tools, approaches, or lessons applied by other authorities be helpful to the United States to further racial equity?

7. What are promising practices or strategies for how anti-trafficking policies and programs can address the compounded barriers at the intersections of systemic racism and other forms of discrimination, such as discrimination against persons with disabilities, persons who are limited English proficient, LGBTQI+ persons, and women and girls?

8. Meaningful stakeholder engagement includes being able to understand each other's spoken language, collective problem-solving and decision-making, equitable partnerships, and collaboration that fosters a sharing of power. What processes or approaches should SPOG agencies have in place to proactively and meaningfully engage individuals with lived experience of human trafficking and communities that are most directly impacted by human trafficking? What are tools and best practices that SPOG agencies should consider to embed racial equity practices into community and stakeholder engagement?

Meeting Accommodation Request

For information on language assistance services, services for individuals with disabilities, or to request accommodation of a disability, please contact *TIPOutreach@state.gov* by April 19, 2023, to give the Department as much time as possible to process the request. Closed captioning and live ASL interpreter services will be available. Determinations for reasonable accommodation will be made on a case-by-case basis.

Cynthia D. Dyer,

Ambassador-at-Large, Office to Monitor and Combat Trafficking in Persons, Department of State.

[FR Doc. 2023–04880 Filed 3–9–23; 8:45 am]

BILLING CODE 4710–11–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36670]

Grafton and Upton Railroad Company—Acquisition and Operation Exemption—CSX Transportation, Inc.

Grafton and Upton Railroad Company (G&U), a Class III carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire by easement from CSX Transportation, Inc. (CSXT), and to continue to operate, approximately 8.4 miles of rail line

(known as the Milford Secondary) between milepost QVG 0 and milepost QVG 8.4 in Milford, Bellingham, and Franklin, Mass. (the Line).[1]

According to the verified notice, this proceeding is related to *Massachusetts Bay Transportation Authority—Acquisition Exemption—CSX Transportation, Inc.,* Docket No. FD 36669. In that proceeding, Massachusetts Bay Transportation Authority (MBTA) filed a verified notice of exemption seeking authority to acquire the physical assets of the Line and another rail line from CSXT, subject to a permanent and exclusive freight common carrier service easement that will be retained by CSXT. *See Mass. Bay Transp. Auth.—Acquis. Exemption—CSX Transp., Inc.,* Docket No. FD 36669, slip op. at 1–2 (STB served March 1, 2023).[2] In the verified notice in this proceeding, G&U states that immediately upon MBTA's closing on the Line's assets, CSXT will assign its new, retained freight easement over the Line to G&U, which will replace G&U's existing easement. G&U further states that it will execute an operating agreement with the MBTA which, together with the new easement, will govern, among other things, MBTA's commuter rail operations and maintenance and G&U's freight common carrier operations over the Line. According to G&U, the agreement assigning the easement from CSXT to G&U provides for an initial term of ten years, subject to three five-year extensions if certain conditions are met.

G&U certifies that its projected annual revenues as a result of this transaction will not exceed $5 million or the threshold required to qualify as a Class III carrier. G&U also certifies that the proposed transaction does not involve a provision or agreement that may limit future interchange with a third-party connecting carrier.

The transaction may be consummated on or after March 24, 2023, the effective date of the exemption (30 days after the verified notice was filed).[3]

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than March 17, 2023 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36670, must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on G&U's representative, James E. Howard, 57 Via Buena Vista, Monterey, CA 93940.

According to G&U, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: March 7, 2023.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023–04906 Filed 3–9–23; 8:45 am]

BILLING CODE 4915–01–P

[1] G&U currently operates over the Line pursuant to an existing easement from CSXT. *See Grafton & Upton R.R.—Acquis. & Operation Exemption—CSX Transp., Inc.,* FD 36444 (STB served Oct. 14, 2020).

[2] As noted in that decision, MBTA also filed a motion to dismiss its notice of exemption on the grounds that its transaction does not require authorization from the Board. *Mass. Bay Transp. Auth.—Acquis. Exemption—CSX Transp., Inc.,* Docket No. FD 36669, slip op. at 1 n.1 (STB served March 1, 2023).

[3] In Docket No. FD 36669, MBTA states that it will consummate its acquisition of the Line's assets once the Board has rendered a favorable decision on the motion to dismiss filed concurrently in that docket and upon effectiveness of the exemption here. *Mass. Bay Transp. Auth.—Acquis. Exemption—CSX Transp., Inc.,* Docket No. FD 36669, slip op. at 2–3 (STB served March 1, 2023).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2022–1202]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Reduction of Fuel Tank Flammability on Transport Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 29, 2022. The FAA's Fuel Tank Flammability Safety rule requires manufacturers to report to the FAA every 6 months on the reliability of the fuel tank flammability reduction systems of their fleet. The data is needed to assure system performance meets that predicted at the time of certification. This collection of information supports the Department of Transportation's strategic goal of safety.

DATES: Written comments should be submitted April 10, 2023.

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: Philip Dang by email at: *Philip.M.Dang@faa.gov* by phone: 206–231–3442.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0710.

Title: Reduction of Fuel Tank Flammability on Transport Category Airplanes.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on Sept 29, 2022 (87 FR 59160). Design approval holders use flammability analysis documentation to demonstrate to their FAA Oversight Office that they are compliant with the Fuel Tank Flammability Safety rule (73 FR 42443). Semi-annual reports submitted by design approval holders provide listings of component failures discovered during scheduled or unscheduled maintenance so that the reliability of the flammability reduction means can be verified by the FAA.

Respondents: Approximately four design approval holders.

Frequency: Every three years.

Estimated Average Burden per Response: 100 hours.

Estimated Total Annual Burden: 800 hours.

Issued in Kansas, Missouri, on March 06, 2023.

Patrick R. Mullen,

Technical Innovations Policy Branch Manager, Policy and Innovation, Aircraft Certification Service.

[FR Doc. 2023–04886 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2000–7257, Notice No. 93]

Railroad Safety Advisory Committee; Notice of Meeting

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: FRA announces the sixty-fourth meeting of the Railroad Safety Advisory Committee (RSAC), a Federal Advisory Committee that provides advice and recommendations to FRA on railroad safety matters through a consensus process. This special meeting of the RSAC will focus on the events related to the February 3, 2023 freight train derailment in East Palestine, Ohio, and include a discussion of potential related safety improvements and possible RSAC tasks and actions.

DATES: The RSAC meeting is scheduled for Monday, March 27, 2023. The meeting will commence at 9:30 a.m. and will adjourn by 4:30 p.m. (all times Eastern Daylight Time). Requests to submit written materials to be reviewed during the meeting must be received by March 17, 2023. Requests for accommodations because of a disability must be received by March 17, 2023.

ADDRESSES: The RSAC meeting will be held at the National Association of Home Builders, located at 1201 15th Street NW, Washington, DC 20005. A final agenda will be posted on the RSAC internet website at *https://rsac.fra.dot.gov/* at least one week in advance of the meeting. Please see the RSAC website for additional information on the committee at *https://rsac.fra.dot.gov/.*

FOR FURTHER INFORMATION CONTACT: Kenton Kilgore, RSAC Designated Federal Officer/RSAC Coordinator, FRA Office of Railroad Safety, (202) 365–3724 or *kenton.kilgore@dot.gov.* Any committee-related request should be sent to Mr. Kilgore.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), FRA is giving notice of a meeting of the RSAC. The RSAC is composed of 51 voting representatives from 26 member organizations, representing various rail industry perspectives. The diversity of the Committee ensures the requisite range of views and expertise necessary to discharge its responsibilities.

Public Participation: The meeting is open to the public. Attendance is on a first-come, first served basis, and is accessible to individuals with disabilities. DOT and FRA are committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, please contact Mr. Kenton Kilgore as listed in the **FOR FURTHER INFORMATION CONTACT** section and submit your request by March 17, 2023. Any member of the public may submit a written statement to the committee at any time. If a member of the public wants the submit written materials to be reviewed by the committee during the meeting, it must be received by March 17, 2023.

Agenda Summary: This special meeting of the RSAC will focus on the events leading up to, during, and following the February 3, 2023 Norfolk Southern Railway Co. freight train derailment in East Palestine, Ohio, as well as suggested safety improvements, and possible RSAC tasks and actions. A detailed agenda for the meeting will be posted on the RSAC internet website at least one week in advance of the meeting. Copies of the minutes of past meetings, along with general information about the committee, are also available on the RSAC internet website at *https://rsac.fra.dot.gov/.*

Issued in Washington, DC.

Amitabha Bose,

Administrator.

[FR Doc. 2023–04914 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Updated Civil Penalty Schedules and Guidelines

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability.

SUMMARY: FRA is issuing this notice to advise all interested stakeholders that it has issued, and made available on its website, updated civil penalty schedules and guidelines (Schedules) to account for inflation. This notice explains FRA's increase to its guideline rail safety civil penalty amounts. This notice also announces FRA's intent to adjust the civil penalty amounts line-by-line on an annual basis for inflation, after this adjustment.

FOR FURTHER INFORMATION CONTACT: Veronica Chittim, Senior Attorney, Office of the Chief Counsel, telephone: 202–480–3410, email: *veronica.chittim@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

FRA is authorized as the delegate of the Secretary of Transportation to enforce the Federal railroad safety and hazardous materials transportation statutes, regulations, and orders, including the civil penalty provisions codified primarily at 49 U.S.C. chs. 51 and 213.[1] FRA currently has safety regulations in 36 parts of the Code of Federal Regulations (CFR) that contain provisions establishing the agency's authority to impose civil penalties if a person[2] violates any requirement in the pertinent portion of a statute, regulation, or order. Out of those 36 CFR parts, 32 contain civil penalty Schedules constituting a statement of agency policy. These Schedules were historically issued as an appendix to the relevant part of the CFR. In 2019, FRA relocated the existing Schedules from the CFR to FRA's website (*https://railroads.dot.gov/legislation-regulations/civil-penalties-schedules-guidelines*).[3] Since 2019, FRA has incorporated updates to the Schedules to account for regulatory changes, to reflect updated minimum and maximum statutory civil monetary penalty (CMP) amounts, and to add Schedules for FRA regulations (*i.e.,* 49 CFR parts 271 and 299).

FRA last published comprehensive, line-by-line revisions to the Schedules of its safety regulations in 1988.[4] The revisions reflected the higher maximum penalty amounts the Rail Safety Improvement Act of 1988 (RSIA of 1988) established.[5] With the exception of the penalties relating to the hours of service laws (49 U.S.C. ch. 211),[6] RSIA

[1] 49 U.S.C. 103 and 49 CFR 1.89; 49 U.S.C. chs. 51, 201–213.

[2] 49 CFR 209.3.

[3] 84 FR 23730 (May 23, 2019).

[4] 53 FR 52918 (Dec. 29, 1988).

[5] Pub. L. 100–342.

[6] The Rail Safety Enforcement and Review Act (RSERA) (Pub. L. 102–365, Sept. 3, 1992), increased the maximum penalty for a violation of the hours of service laws, from $1,000 to $10,000, and in some cases to $20,000, making these penalty amounts consistent with those of FRA's other regulatory provisions. RSERA also increased the

of 1988 raised the maximum penalty for an ordinary violation from $2,500 to $10,000 (ordinary maximum) and to $20,000 for a grossly negligent violation or pattern of repeated violations that has caused an imminent hazard or death or injury to individuals, or has caused death or injury (aggravated maximum). Therefore, FRA published amendments to the Schedules to ''give effect to the full range of civil penalties . . . permitted to be assessed for violation of specific regulations.'' [7] In these amendments, FRA revised not only the ordinary and aggravated maximum CMP amounts per violation, but also the individual, line-item penalties for specific sections or subsections of the regulations.

Since the publication of the Schedules in 1988, FRA has periodically adjusted its minimum CMP and its ordinary and aggravated maximum CMPs to conform to the mandates of the Federal Civil Penalties Inflation Adjustment Act of 1990 (Inflation Act).[8] The Inflation Act required each agency to: (1) adjust by regulation each maximum CMP, or range of minimum and maximum CMPs, within that agency's jurisdiction; and (2) adjust those penalty amounts once every four years thereafter, to reflect inflation.[9] FRA periodically reviewed its minimum CMP and ordinary and aggravated maximum CMPs as the Inflation Act required and adjusted them as appropriate.[10]

The Rail Safety Improvement Act of 2008 (RSIA) increased the ordinary and aggravated maximum CMPs to $25,000 and $100,000, respectively.[11] In 2008, FRA adjusted its minimum CMP from $550 to $650 under the Inflation Act, and also adopted $25,000 as the ordinary maximum and $100,000 as the aggravated maximum CMPs required by the RSIA.[12] Subsequently, in 2012, FRA adjusted the aggravated maximum CMP for inflation to $105,000, but kept the minimum and ordinary maximum CMPs unchanged.[13]

Under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Inflation Act), agencies were required to make a catch-up adjustment for the minimum, ordinary maximum, and aggravated maximum CMPs, followed by annual inflation adjustments.[14] FRA has adjusted the statutory minimum, ordinary maximum, and aggravated maximum CMPs pursuant to the 2015 Inflation Act, with the most recent adjustment occurring on January 6, 2023.[15]

FRA's practice has been to issue Schedules assigning to each section or subsection of the regulations specific dollar amounts for initial penalty assessments. These Schedules (and all line-item penalty amounts found within them) are statements of agency policy that specify the penalty that FRA will ordinarily assess for the violation of a particular section or subsection of a safety regulation, and are published to inform members of the regulated community of the penalty FRA will likely assess for a given violation within the range of the statutory minimum to the aggravated maximum CMP. The Schedules are not regulations nor are they subject to notice-and-comment requirements. The Schedules provide guidance on FRA's policy in predictable situations, but they do not prevent FRA from using the full range of penalty authority when circumstances warrant. Thus, regardless of the amounts shown in the Schedules, FRA continues to reserve the right to assess, within the range established by the rail safety statutes (49 U.S.C. ch. 213) or by regulation under the 2015 Inflation Act, an amount other than that listed in the Schedules based on the circumstances of the alleged violation.

The Schedules included in these statements of agency policy continue to provide guideline penalty amounts for two categories of violations: ordinary (non-willful) and willful. Each Schedule lists the CFR section or subsection in the left-hand column, sometimes with additional designations to distinguish different types of violations (penalty codes) of the section or subsection, to facilitate the assessment of civil penalties.[16] The corresponding guideline penalty amount for an ordinary violation and then the guideline penalty amount for a willful violation are listed. The ordinary penalties apply to railroads or other respondents, except individuals, while the ''willful'' column applies to willful violations committed by railroads or other respondents, including individuals.

Updated Civil Penalty Schedules

FRA is updating, line-by-line, FRA's civil penalty Schedules to account for inflation. Although the 2015 Inflation Act did not require FRA to adjust individual, line-item penalty amounts, Congress' recognition in that Act of the negative impact that inflation has on the deterrent effect of FRA's civil penalties, and the fact FRA has never adjusted each of its civil penalties to specifically account for inflation, prompted FRA to update these statements of agency policy. FRA believes the new inflation-adjusted penalty amounts in these statements of agency policy will preserve the deterrent effects of the CMPs, supporting FRA's mission to make the United States' rail system safer.

Many of FRA's existing CMP guideline amounts are below the 2023 statutory minimum CMP amount of $1,052.[17] To address this issue both specifically for the existing $1,000 guideline CMPs and to combat the erosion of the deterrent effect of FRA's civil penalties in a consistent manner, FRA is updating all rail safety CMP guideline amounts.

Effective for violations occurring on or after March 8, 2023, FRA has increased all rail safety penalties by multiplying the base, pre-adjusted penalty, by two. For example, a base penalty of $2,500 will increase to $5,000. Beginning in 2024, FRA intends to annually adjust all of its Schedules by a fixed inflation rate factor (using the Consumer Price Index), similar to the calculation used to adjust the statutory minimum and maximum CMPs. FRA will continue to post such inflation updates to its Schedules on FRA's website (*https://railroads.dot.gov/legislation-regulations/civil-penalties-schedules-guidelines*).

Conclusion

To promote railroad safety by enhancing and maintaining the deterrent effect of the civil penalty program, FRA is doubling its guideline

minimum penalty from $250 to $500 for all of FRA's regulatory provisions.

[7] 53 FR 52918.

[8] Public Law 101–410, 104 Stat. 890, 28 U.S.C. 2461 note, as amended by Sec. 31001(s)(1) of the Debt Collection Improvement Act of 1996, Public Law 104–134, 110 Stat. 1321–373, Apr. 26, 1996.

[9] *Id.*

[10] *See, e.g.,* 63 FR 11618 (Mar. 10, 1998); 69 FR 30591 (May 28, 2004); 72 FR 51194 (Sept. 6, 2007).

[11] Public Law 110–432, Div. A, Sec. 302.

[12] *Id.;* 74 FR 15387 (Apr. 6, 2009).

[13] 77 FR 24415 (Apr. 24, 2012).

[14] Public Law 114–74, Sec. 701 (Nov. 2, 2015).

[15] *See* 49 CFR part 209, appendix A. Effective January 6, 2023, the minimum CMP was raised from $976 to $1,052, the ordinary maximum CMP was raised from $31,928 to $34,401, and the aggravated maximum CMP was raised from $127,712 to $137,603. *See* 88 FR 1114.

[16] The only exception is 49 CFR part 231; the left-hand column of the Schedule lists the FRA defect codes for that part, and not the corresponding CFR sections. This is because the defect codes are organized by the type of safety appliance, which makes them easier to use than the section numbers of part 231, which are organized primarily by car or locomotive type. Nevertheless, if necessary, every defect code can be traced to a specific regulatory provision in part 231 or statutory provision in 49 U.S.C. ch. 203, or both.

[17] *See, e.g.,* a guideline base CMP for a non-willful violation of 49 CFR 213.241, *Inspection records,* $1,000.

penalties to account for inflation. Beginning in 2024, FRA expects to annually adjust its civil penalty Schedules indexed to the rate of inflation. All updates to these statements of agency policy can be found on FRA's website (*https://railroads.dot.gov/legislation-regulations/civil-penalties-schedules-guidelines*).

Issued in Washington, DC.

Allison Ishihara Fultz,

Chief Counsel.

[FR Doc. 2023–04957 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Toyota Motor North America, Inc.

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Toyota Motor North America, Inc.'s (Toyota) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its Crown vehicle line beginning in model year (MY) 2024. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

DATES: The exemption granted by this notice is effective beginning with the 2024 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. Chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition the Secretary of Transportation for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that the Secretary decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers Toyota Motor North America, Inc.'s (Toyota) petition for its Crown vehicle line beginning in MY 2024.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Toyota petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2024. Toyota petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsections 8 through 21) of C.R.C, c. 1038.114, *Theft Protection and Rollaway Prevention (in effect March 30, 2011),* as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, *Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization* (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), *Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with Regard to Their Alarm System (AS)* in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), *Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use* in effect on February 10, 2009.

[2] 49 U.S.C. 33106(d).

reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Toyota's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Toyota's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

II. Toyota's Petition for Exemption

In a petition dated October 24, 2022, Toyota requested an exemption from the parts-marking requirements of the theft prevention standard for the Crown vehicle line beginning with MY 2024.

In its petition, Toyota provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Crown vehicle line. Toyota stated that its MY 2024 Crown vehicle line will be installed with an engine immobilizer device as standard equipment, as required by 543.6(a)(1). Toyota stated that it will offer an entry and start system on its Crown vehicle line. Specifically, key components of the ''smart entry and start'' system will include a certification engine control unit (ECU), engine switch, security indicator, door control receiver, electrical key, ID code box, and an HV ECU. Toyota stated that there will also be position switches installed on the vehicle to protect the hood and doors from unauthorized tampering/opening. Toyota further explained that locking the doors can be accomplished through use of a key, wireless switch or its smart entry system, and that unauthorized tampering with the hood or door without using one of these methods will cause the position switches to trigger its antitheft device to operate. Toyota will also incorporate an audible and visual alarm system on its vehicle line, when unauthorized access is attempted, the horn will sound and the lights will flash.

Pursuant to Section 543.6(a)(3), Toyota explained that its ''smart entry and start'' system is activated when the engine switch is pushed from the ''ON'' ignition status to any other status. The certification ECU then performs the calculation for the immobilizer and the immobilizer signals the HV ECU to activate the device. Toyota also explained that its ''smart entry and start'' system is deactivated after the driver pushes the engine switch and the key is verified, the certification ECU and ID code box receives verification of a valid key, the certification ECU allows the HV ECU to start the engine. Toyota stated that in its system, a security indicator is installed notifying the user and others inside and outside the vehicle with the status of the immobilizer. Toyota further explained that the security indicator flashes continuously when the immobilizer is activated, and turns off when it is deactivated.

As required in section 543.6(a)(3)(v), Toyota provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Toyota conducted tests based on its own specified standards. Toyota provided a detailed list of the tests conducted (*i.e.,* high and low temperature operation, strength, impact, vibration, electro-magnetic interference, etc.). Toyota stated that it believes that its device is reliable and durable because it complied with its own specific design standards and the antitheft device is installed on other vehicle lines for which the agency has granted a parts-marking exemption. As an additional measure of reliability and durability, Toyota stated that its vehicle key cylinders are covered with casting cases to prevent the key cylinder from easily being broken. Toyota further explained that there are approximately 1,000 combinations for inner cut keys which makes it difficult to unlock the doors without using a valid key because the key cylinders would spin out and cause the locks to not operate.

Toyota stated that its Crown vehicle has already been equipped with an immobilizer since MY 2023 as standard equipment. Toyota also stated that at the time of the petition submission, theft rate data for the MY 2024 Crown vehicle line is not available. However, Toyota compared its proposed device to other devices NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements. Toyota compared its proposed device to that which has been installed on the Toyota Corolla vehicle line, which was granted a parts-marking exemption from 49 CFR part 541 by the agency beginning with MY 2012 vehicles. Toyota also referenced the NHTSA theft rate data published for the Corolla before and after being equipped with a standard immobilizer showing the average theft rate drop to 2.1 per 1,000 vehicles (2005–2008) compared to 4.0 per 1,000 vehicles (1996–1999). Toyota stated that the data for the Corolla represents an approximate 47.5% decrease in a theft rate with an immobilizer. Therefore, Toyota concluded that the antitheft device proposed for its Crown vehicle line is no less effective than those devices on the lines for which NHTSA has already granted full exemption from the parts-marking requirements. Toyota stated that it believes that installing the immobilizer device as standard equipment reduces the theft rate for the Crown vehicle line and expects it to

[3] 49 CFR 543.6(a)(3).

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

experience comparable effectiveness and ultimately be more effective than parts-marking labels.

III. Decision To Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Toyota has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Toyota provided about its antitheft device. NHTSA believes, based on Toyota's supporting evidence, the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Toyota's antitheft device will provide the five types of performance features listed in section 543.6(a)(3): promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

If Toyota decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Toyota wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.'' [7]

The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if Toyota contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

For the foregoing reasons, the agency hereby grants in full Toyota's petition for exemption for the Crown vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2024 vehicles.

[7] The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if a manufacturer with an exemption contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

Issued under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2023–04868 Filed 3–9–23; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On March 3, 2023, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. LENSKAYA, Elena Anatolievna (Cyrillic: ЛЕНСКАЯ, Елена Анатольевна) (a.k.a. LENSKAYA, Yelena), Moscow, Russia; DOB 22 Jan 1979; nationality Russia; Gender Female; Tax ID No. 770905658030 (Russia); Judge of the Basmannyy District Court in Moscow (individual) [GLOMAG].

   Designated pursuant to section 1(a)(ii)(A) of Executive Order 13818 of December 20, 2017, "Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption," 82 FR 60839 (Dec. 26, 2017) (E.O. 13818) for being a foreign person who is responsible for or complicit in, or has directly or indirectly engaged in, serious human rights abuse.

2. MIKHEEV, Danila Yurievich (Cyrillic: МИХЕЕВ, Данила Юрьевич) (a.k.a. MIKHEYEV, Danila Yuryevich), Moscow, Russia; DOB 01 Mar 1999; nationality Russia; Gender Male; Tax ID No. 504414685889 (Russia) (individual) [GLOMAG].

   Designated pursuant to section 1(a)(iii)(A)(1) of E.O. 13818 for being a foreign person who has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, serious human rights abuse that is conducted by a foreign person.

3. ZADACHIN, Andrei Andreevich (Cyrillic: ЗАДАЧИН, Андрей Андреевич), Moscow, Russia; DOB 22 Aug 1990; nationality Russia; Gender Male; Tax ID No. 771577190559 (Russia); Justice Major (individual) [GLOMAG].

   Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being a foreign person who is responsible for or complicit in, or has directly or indirectly engaged in, serious human rights abuse.

Dated: March 3, 2023.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2023–04989 Filed 3–9–23; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Annual Return/Report of Employee Benefit Plan

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Internal Revenue Service (IRS), 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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the Annual Return/Report of Employee Benefit Plan.

DATES: Comments should be received on or before April 10, 2023 to be assured of consideration.

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. Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Annual Return/Report of Employee Benefit Plan.

OMB Control Number: 1545–1610.

Form Number: 5500 and associated Schedules, and 5558.

Abstract: The Annual Return/Report of Employee Benefit Plan is an annual information return filed by employee benefit plans. The IRS uses this information for a variety of matters, including ascertainment whether a qualified retirement plan appears to conform to requirements under the Internal Revenue Code or whether the plan should be audited for compliance. Form 5500–EZ is an annual return filed by a one participant (owners/partners and their spouses) retirement plan or a foreign plan to satisfy certain annual reporting and filing requirements imposed by the Internal Revenue Code (Code). Form 5558 will be used by the IRS to grant extension request for filing the 5500 series and the 8955–SSA forms. The IRS uses this data to

determine if the plan appears to be operating properly as required under the Code or whether the plan should be audited.

Current Actions: IRS is adding Form 5558 to the OMB approval for 1545–1610. Additionally, IRS is making the following revisions to the Form 5558 to allow for electronic filing with the Department of Labor's (DOL) ERISA Filing Acceptance System (EFAST2).

Currently, Form 5558 is used by a filer to request an extension of time to file Form 5500 series, Form 8955–SSA as well as the Form 5330, *Return of Excise Taxes Related to Employee Benefit Plans.* Form 5558 does not extend the time to pay the excise taxes. Any tax due for Form 5330 filers must be paid with Form 5558 for the application for an extension of time to file Form 5330.

The DOL EFAST2 system will not take the IRS tax payment. Thus, the IRS will revise Form 5558 to remove the items about the extension of time to file Form 5330. This will allow DOL to electronically collect the form. The Form 5558 will be used to solely request extensions on the Form 5500 series and Form 8955–SSA. The payment information from Form 5558 will be incorporated into Form 8868. The Form 8868 will be revised to allow extensions for Form 5330 and payment of excise tax due. Form 8868 will only allow for the extension to file, and will not extend the payment of the excise tax. The pension plan burden for the Form 8868 revision will be covered under 1545–0575.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals and households, not-for profit institutions, and farms.

Estimated Total Number of Respondents: 1,471,958.

Estimated Total Number of Responses: 1,471,958.

Estimated Total Frequency of Response: 1.

Estimated Total Average of Hours per Response: 2.4.

Estimated Total Annual Burden Hours: 2,138,922.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2023–04930 Filed 3–9–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Matching Program

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of a new matching program.

SUMMARY: The Department of Veterans Affairs (VA) has an 18 month computer matching agreement (CMA) agreement with the Federal Bureau of Prisons (BOP) regarding Veterans, VA beneficiaries, and caregivers who are in federal prison and are also in receipt of compensation and pension benefits. The purpose of this CMA is to re-establish the agreement between VA and the United States Department of Justice (DOJ), BOP. BOP will disclose information about individuals who are in federal prison. VBA will use this information as a match for recipients of Compensation and Pension benefits for adjustments of awards.

DATES: Comments on this matching program must be received no later than 30 days after the date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the new agreement will become effective a minimum of 30 days after the date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary. This matching program will be valid for 18 months from the effective date of this notice.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to the computer matching agreement between the Department of Veterans Affairs and the Federal Bureau of Prisons. Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Eric Robinson (VBA), 202–443–6016, *Eric.Robinson3@va.gov.*

SUPPLEMENTARY INFORMATION: This matching program between VA and BOP identifies VA beneficiaries who are in receipt of certain VA benefit payments and who are confined for a period exceeding 60 days due to a conviction for a felony or a misdemeanor. VA uses the BOP records provided in the match to update the master records of VA beneficiaries receiving benefits and to adjust their VA benefits, accordingly, if needed. This agreement sets forth the responsibilities of VA and BOP with respect to information disclosed pursuant to this agreement and takes into account both agencies' responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a, as amended by the Computer Matching and Privacy Protection Act of 1988, as amended, and the regulations promulgated thereunder, including computer matching portions of a revision of OMB Circular No. A–130, 81 FR 49689 dated July 28, 2016.

Participating Agencies: The United States Department of Veterans Affairs (VA), as the matching recipient agency and the United States Department of Justice (DOJ), Federal Bureau of Prisons (BOP) as the matching source agency.

Authority for Conducting the Matching Program: The legal authority to conduct this match is 38 U.S.C. 1505, 5106, and 5313. Section 5106 requires any Federal department or agency to provide VA such information as VA requests for the purposes of determining eligibility for, or the amount of VA benefits, or verifying other information with respect thereto. Section 1505 provides that no VA pension benefits shall be paid to or for any person eligible for such benefits, during the period of that person's incarceration as the result of conviction of a felony or misdemeanor, beginning on the sixty-first day of incarceration. Section 5313 provides that VA compensation or dependency and indemnity compensation above a specified amount shall not be paid to any person eligible for such benefit, during the period of that person's incarceration as the result of conviction of a felony, beginning on the sixty-first day of incarceration.

Purpose(s): The purpose of this matching program between VA and BOP to identify those veterans and VA beneficiaries, including VA caregivers, such as for those participating in VA's Program of Comprehensive Assistance for Family Caregivers (PCAFC), who are in receipt of certain VA benefit payments and who are confined for a period exceeding 60 days due to a conviction for a felony or a misdemeanor. VA has the obligation to reduce or suspend compensation, pension, and dependency and indemnity compensation benefit payments to veterans and VA beneficiaries on the 61st day following conviction and incarceration in a Federal, State, or Local institution for a felony or a misdemeanor.

Categories of Individuals:

Veterans who have applied for compensation for service-connected disability under 38 U.S.C. Chapter 11.

Veterans who have applied for nonservice-connected disability under 38 U.S.C. Chapter 15.

Veterans entitled to burial benefits under 38 U.S.C. Chapter 23.

Surviving spouses and children who have claimed pensions based on nonservice-connected death of a veteran under 38 U.S.C. Chapter 15.

Surviving spouses and children who have claimed death compensation based on service-connected death of a veteran under 38 U.S.C. Chapter 11.

Surviving spouses and children who have claimed dependency and indemnity compensation for service-connected death of a veteran under 38 U.S.C. Chapter 13.

Parents who have applied for death compensation based on service-connected death of a veteran under 38 U.S.C. Chapter 11.

Parents who have applied for dependency and indemnity compensation for service-connected death of a veteran under 38 U.S.C. Chapter 13.

Individuals who applied for educational assistance benefits administered by VA under title 38 of the U.S. Code.

Individuals who applied for educational assistance benefits maintained by the Department of Defense under title 10 of the U.S. Code that are administered by VA.

Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Emergency Veterans' Job Training Act of 1983, Public Law 98–77.

Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Service Members Occupational Conversion and Training Act of 1992, Public Law 102–484.

Representatives of individuals covered by the system.

Fee personnel who may be paid by the VA which includes caregivers.

Categories of Records: The record, or information contained in the record, may include identifying information such as social security number, last name, first name, middle name, suffix name, date of birth, date of computation begins, length of sentence, place of current confinement or destination of confinement if in-transit, **Federal Register** number, type of offense, and date of scheduled or actual release.

System(s) of Records: Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA (58 VA 21/22/28)'', published at 74 FR 29275 (June 19, 2009), last amended at 86 FR 61858 (November 8, 2021). VA will additionally match SSNs received from BOP with SSNs in VA's system of records entitled, '' 'Caregiver Support Program-Caregiver Record Management Application (CARMA)-VA'' (197VA10)'', published at 86 FR 18588 (April 9, 2021), routine use 14. Justice/BOP–005,'' published on June 7, 1984 (48 FR 2371 1), republished on May 9, 2002 (67 FR 31371), January 25, 2007 (72 FR 3410) and April 26, 2012 (77 FR 24982) and last modified on February 19, 2013 (78 FR 1 1575), routine use (i).

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John Oswalt, Chief Privacy Officer and Chair of the Data Integrity Board, Department of Veterans Affairs approved this document on March 2, 2023 for publication.

Dated: March 7, 2023.

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

[FR Doc. 2023–04905 Filed 3–9–23; 8:45 am]

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 900

Mammography Quality Standards Act; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. FDA–2013–N–0134]

RIN 0910–AH04

Mammography Quality Standards Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). We are issuing updates to modernize the regulations by incorporating current science and mammography best practices. These updates are intended to improve the delivery of mammography services by strengthening the communication of healthcare information; allowing for more informed decision making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

DATES: This rule is effective on September 10, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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: Preetham Sudhaker, Division of Mammography Quality Standards (DMQS), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–5911.

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I. Executive Summary

A. Purpose of the Final Rule

Mammography is an x-ray imaging examination used to identify signs of breast cancer. For patients to receive the full benefit of mammography, the service must be of high quality, including performance of the examination by qualified technologists, using equipment that is tested and properly functioning; interpretation by qualified physicians; and clear and prompt communication of results to patients and their referring healthcare providers. The MQSA establishes uniform baseline Federal standards designed to ensure, among other things, that all patients nationwide have access to quality mammography services. The MQSA implementing regulations address, among other things, standards for accreditation bodies and certifying agencies and mammography quality standards for facilities, such as qualifications of personnel at mammography facilities, standards for mammography equipment, the content and terminology for mammography reports, the requirement to establish a quality assurance program, standards and timing for quality assurance testing, standards for clinical image quality, recordkeeping, communication of results, and clinical image review by the facility's accrediting body. Based on technology changes in mammography and our experience with the administration of the MQSA program, FDA is modernizing and updating the regulations as well as improving the information, including breast density information, provided by mammography facilities to patients and their healthcare providers. This final rule requires that the summary of the mammography report written in lay terms (''lay summary'') that is provided to patients identifies whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density. The rule also establishes four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider.

B. Legal Authority

The MQSA was enacted on October 27, 1992, and is codified, as amended in 1998 and 2004, under section 354 of the Public Health Service (PHS) Act. Public Law 102–539, 2, 106 (1992), *codified as amended at* 42 U.S.C. 263b. Under the MQSA, all mammography facilities, except facilities of the Department of Veterans Affairs (VA), must be accredited by an approved accreditation body (AB) and certified by FDA (or an approved State certification agency) to provide mammography services. FDA is amending the mammography regulations established under the PHS Act, and sections of the FD&C Act.

C. Summary of the Major Provisions of the Final Rule

FDA is making three categories of improvements to our mammography regulations: improvements that address changes in mammography technology; improvements that enhance enforcement of quality standards; and improvements in the way mammography results are categorized, reported, retained, and transferred to patients and healthcare providers. Specifically, in this final rule FDA is making the following amendments:

- New and amended provisions related to technology that, among other things, update several equipment and quality control provisions in the regulations to address current technology, including digital mammography;
- Improvements that enhance enforcement that, among other things:
  - Require that mammograms submitted for interpretation be presented in the mammographic modality in which they were originally produced, and not be copied or digitized from hardcopy original images, which could adversely affect the accuracy of interpretation;
  - Prohibit accreditation bodies from accepting an application for accreditation from a facility that has failed to become accredited after three consecutive attempts until 1 year after the most recent accreditation failure;
  - Expressly state that a facility's certificate may be suspended or revoked due to a failure to comply with requests by FDA, the State certification agency, or the AB for records, including clinical images for an additional mammography review (AMR), or with requests by current or former facility personnel for records documenting their qualifications;
  - Add the State certification agency as an entity that may initiate an AMR, which can help detect quality issues, and also to state expressly that FDA and the State certification agency can notify patients and their providers individually or through the mass media when a facility is unable or unwilling to perform a required patient and referring physician notification (PPN), which would help to ensure that patients and providers are informed of serious risks to human health resulting from mammography that fails to meet quality standards;
  - Require that, before a facility closes or no longer provides mammography services, it must make arrangements for access by patients and healthcare providers to mammography images and reports; and
  - Require facilities to provide personnel with copies of their MQSA qualification records, which are often needed to work at additional or new facilities.
- Improvements in the way mammography results are categorized, reported, retained, and transferred to patients and healthcare providers that, among other things:
  - Require that the mammographic examination report include the facility name and location (at a minimum, the city, State, ZIP code, and telephone number of the facility), in order to help to ensure that healthcare providers can obtain the necessary information to enable them to assist patients in making informed healthcare decisions;
  - Change the explanatory language in one final assessment category (''Benign'') to promote greater consistency and accuracy in the use of the category, and add three new categories of mammographic assessment to the existing categories in the regulations, which will allow mammography facilities to precisely classify and communicate findings;
  - Add a specific, required timeframe for facilities to send mammography reports to healthcare providers and the summary written in lay terms to patients whose mammograms have either ''Suspicious'' or ''Highly Suggestive of Malignancy'' final assessment categories, which could lead to earlier definitive tissue diagnosis of malignancy and earlier start of treatment, and avoid, for the patient, the anxiety of a protracted waiting period;
  - Require reporting to patients and healthcare providers to include an assessment of breast density, in order to provide them with additional information about their mammography and the potential limitations of their mammogram results so that patients and their healthcare providers can make informed healthcare decisions by;
    - Retaining the two categories of density in the patient lay summary, but changing the wording from the comparative terms ''high density'' and ''low density'' to ''dense'' and ''not dense,'' in order to align with clinical practice and improve clarity to the patient.
    - Revising the written lay summary of the results provided to the patient to contain one of the following breast density notification statements. The non-dense breast notification (see § 900.12(c)(2)(iii) in this final rule) now states, ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.'' The dense breast notification (see § 900.12(c)(2)(iv) in this final rule) now states, ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.''
    - Requiring that the written report of the results of the mammographic examination provided to the healthcare provider include information concerning an overall assessment of breast density, classified in one of the following categories: (A) ''The breasts are almost entirely fatty.'' (B) ''There are scattered areas of fibroglandular density.'' (C) ''The breasts are heterogeneously dense, which may obscure small masses.'' (D) ''The breasts are extremely dense, which lowers the sensitivity of mammography.''
  - Require each mammography facility to implement policies and procedures to minimize the loss of mammography images and reports because the loss of these records can have a significant, negative impact on clinical care, and also specify the timeframe within which facilities must transfer original mammograms and copies of reports to patients, healthcare providers, and others because delays in the transfer of these records can lead to delays in diagnosis or treatment; and
  - Clarify the minimum information that facilities must collect during the mammography medical outcomes audit because calculating and tracking these values is important to the evaluation of accuracy in detecting breast cancer, allowing facilities and interpreting physicians to review their performance and enact quality improvement measures.

D. Costs and Benefits of the Final Rule

The quantified benefits of this rule are derived from reduced mortality and breast cancer treatment costs resulting from the breast density reporting requirements. The estimate of annualized benefits over 10 years ranges from $12.99 million to $232.69 million at a 7 percent discount rate and $8.50 million to $266.09 million at a 3 percent discount rate. Other benefits that we are not able to quantify include reduced cancer morbidity and improvements in the accuracy of mammography by

improving quality control and strengthening the medical audit. The costs of the final rule include costs to mammography facilities to comply with the requirements and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years ranges from $28.87 million to $45.42 million at a 7 percent discount rate with a primary value of $36.31 million. Using a 3 percent discount rate, the annualized costs range from $27.61 million to $44.16 million with a primary value of $35.05 million.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation or acronym	What it means
AB	Accreditation Body.
ACR	American College of Radiology.
ACS	American Cancer Society.
AMR	Additional Mammography Review.
BICOE	Breast Imaging Centers of Excellence.
BI–RADS	Breast Imaging—Reporting and Data System.
CAD	Computer-Aided Detection.
CD	Compact Discs.
CDC	Centers for Disease Control and Prevention.
CDR	Cancer Detection Rate.
CDRH	Center for Devices and Radiological Health.
CFR	Code of Federal Regulations.
CRCPD	Conference of Radiation Control Program Directors, Inc..
DBT	Digital Breast Tomosynthesis.
DICOM	Digital Imaging and Communication in Medicine.
DMQS	Division of Mammography Quality Standards.
ERG	Eastern Research Group.
FDA, Agency, or we	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FFDM	Full-Field Digital Mammography.
FRIA	Final Regulatory Impact Analysis.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
IP	Interpreting Physician.
MBI	Molecular Breast Imaging.
MQSA	Mammography Quality Standards Act of 1992.
MQSRA	Mammography Quality Standards Reauthorization Acts of 1998 and 2004.
MRI	Magnetic Resonance Imaging.
NAPBC	National Accreditation Program for Breast Centers.
NMQAAC	National Mammography Quality Assurance Advisory Committee.
OMB	Office of Management and Budget.
PACS	Picture Archiving and Communication System.
PGHS	Policy Guidance Help System.
PHS Act	Public Health Service Act.
PPN	Patient and Referring Physician Notification.
PPV	Positive Predictive Value.
QC	Quality Control.
QI	Quality Indicator.
SCA	State Certification Agency.
U.S.C.	United States Code.
USPSTF	U.S. Preventive Services Task Force.
VA	Department of Veterans Affairs.

III. Background

According to the Centers for Disease Control and Prevention (CDC), in 2018, the most recent year for which numbers are available, over 254,000 women were diagnosed with breast cancer, and more than 42,000 women died of the disease (Ref. 1). According to the National Cancer Institute of the National Institutes of Health, in 2020, over 276,000 women were projected to be diagnosed with breast cancer, and over 42,000 women were projected to die of the disease (Ref. 2). Breast cancer is rare in men, with approximately 2,300 new cases and 500 deaths reported in the United States in 2017, according to the CDC (Ref. 3). Among women, however, breast cancer is now the most common non-skin cancer and the second leading cause of cancer deaths after lung cancer (Ref. 4). There are also disparities in both the incidence of breast cancer, and in mortality from breast cancer, by both race and ethnicity. In 2019, the latest year for which incidence data are available, in the United States, 30,450 new cases of breast cancer were reported among Black, Non-Hispanic women, and 6,600 Black, Non-Hispanic women died of this cancer. For every 100,000 Black, Non-Hispanic women, 128 new breast cancer cases were reported and 28 Black, Non-Hispanic women died of this cancer (Ref. 1). Health disparity and equity considerations may exist as they relate to mammography practice and density notification, and we have considered sociodemographic differences in mammography practice and outcomes. This final rule provides standard requirements that help to ensure that all patients and providers receive complete and consistent breast density information in mammography reports.

Early detection of female breast cancer, typically involving mammography, is the best means of preventing deaths that can result if the diagnosis is delayed until the onset of more advanced symptoms (Ref. 5). Mammography is a type of medical imaging that uses x-rays to create images (mammograms) of the internal structures of the breasts. There are three types of mammography referred to in

this document: screen-film mammography, full field digital mammography, and digital breast tomosynthesis. In screen-film mammography, x-rays are transmitted through the breast and expose a sheet of x-ray film enclosed in a cassette. In full field digital mammography, the x-rays go through to an image receptor that is a radiation-sensitive electronic device or plate. Images are displayed on a computer workstation, and can, for example, be digitally magnified. Digital breast tomosynthesis also uses an electronic image receptor and a computer workstation, and obtains multiple images at different angles around the breast, then uses a computer to reconstruct a series of parallel images that resemble slices through the breast.

Mammography can help detect breast cancer in its earliest, most treatable stages, when it is too small to be felt or detected by any other method (Ref. 6).

However, as noted by the Government Accountability Office (GAO), a mammogram is among the most difficult radiographic images to interpret (Ref. 7). The mammogram must be of high quality for accurate image interpretation. If the image quality is poor, the interpreter may miss a cancerous lesion. Such a false negative diagnosis could delay treatment and result in an avoidable death or increased morbidity. It is equally true that poor quality images or inaccurate interpretations can lead to a false positive diagnosis when normal tissue is misinterpreted as abnormal. This could lead to needless anxiety for the patient, costly additional testing, and unnecessary biopsies.

A. Need for Amendments to Mammography Regulations

Most of the requirements in our mammography regulations are over 20 years old. As described below and in the proposed rule (84 FR 11669, March 28, 2019), major developments in understanding relating to the importance of certain breast anatomy on breast cancer risk have occurred, and FDA believes these developments should be reflected in our nationwide standard. In addition, we are updating our mammography regulations in response to several gaps that we have identified as we have implemented the current regulations. Current regulations do not require that a notification of breast density be part of the report provided to the healthcare provider or the lay summary provided to the patient. However, there is increasing interest in breast density reporting, and States are taking action. Between 2009 and June 2021, 38 States have passed laws mandating notification of breast density (Ref. 8). These State laws impose requirements that vary from State to State. To ensure all patients receive breast density information from their mammograms, and that such required baseline information is consistent, FDA is amending the mammography reporting requirements to require that the written report of the results of the mammographic examination provided to the healthcare provider and the lay summary of the results provided to the patient also include information concerning patient breast density. FDA is also requiring that both the mammography report and lay summary include basic mammography facility identification information. Technology has also advanced since the regulations were issued, so the amended regulations will make changes to reflect current mammography best practices and technologies.

B. Summary of Comments to the Proposed Rule

In the **Federal Register** of March 28, 2019, FDA published a rule proposing amendments to the MQSA regulations. The comment period for the proposed rule closed on June 26, 2019. FDA received many comments on the proposed rule from several entities including medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. While several comments object to particular sections or subsections of the proposed rule, almost all comments voice support for the objective intent of the proposed rule, to establish updates to modernize the MQSA regulations to incorporate current science and mammography best practices.

Some comments raise concerns or request clarification regarding:

- the scope of the MQSA regulations,
- failure of facility accreditation,
- retention of personnel records,
- mammography reports (including assessment categories) and lay summaries,
- breast density notification to patients and referring providers,
- requirements for image retention, transfer of original images, and release of copies,
- the mammography medical outcomes audit,
- patient and provider notification,
- the availability and use of various imaging modalities, and
- issues related to clinical decision-making.

C. General Overview of the Final Rule's Changes From the Proposed Rule

FDA considered all comments received on the proposed rule and made changes, primarily for clarity and accuracy and to improve understanding of breast density notification language to healthcare providers and patients. On its own initiative, FDA is also making minor technical changes to make the withdrawal provisions clearer. The changes from the proposed rule include the following significant revisions, additions, and removals to the codified section:

- add or substitute the term ''provider'' or ''healthcare provider'' in several paragraphs in place of references to referring physician (§§ 900.2(c)(2), 900.2(k), 900.2(ii), 900.4(f)(1)(ii)(B), and 900.12(j)),
- revise language to clarify that no AB shall accept an application for accreditation from a facility that has had three consecutive failures (§ 900.4(a)(6)(ii)),
- include additional language requiring that facilities must retain personnel qualification records of former employees for at least 24 months (§ 900.12(a)(4)),
- remove the proposed term ''digital accessory components'' and clarify the premarket requirements for devices used in mammography (§ 900.12(b)(2)(i)),
- include additional language clarifying that the required final assessment statements are only the words or phrases in quotation marks (§ 900.12(c)(1)(iv)),
- revise the requirement that clinical findings or symptoms in a patient whose mammogram assessment is negative or benign shall be ''documented and addressed,'' rather than ''explained'' (§ 900.12(c)(1)(iv)(A) and (B)),
- correct the reference to the two categories of breast density that shall be included in the lay summary provided to the patient (§ 900.12(c)(2)),
- include additional language clarifying the deadline for sending the mammography report to a self-referred patient when the assessment is ''Suspicious'' or ''Highly Suggestive of Malignancy'' (§ 900.12(c)(2)(i)),
- include additional language clarifying the situations in which a facility must maintain a system for referring self-referred patients to a healthcare provider (§ 900.12(c)(2)(ii)),
- revise the breast density notification language that must be included in lay summaries provided to patients with non-dense and dense tissue, respectively (§ 900.12(c)(2)(iii) and (iv)),

• add language clarifying the length of time a facility is required to maintain the original mammograms and mammography reports in a permanent medical record of the patient by clarifying it is for the longer of the applicable Federal timeframes, or the mandated State or local timeframes (§ 900.12(c)(4)(i)),

• add language clarifying that a facility that ceases to perform mammography but continues to operate as a medical entity may retain, rather than transfer, its mammography records (§ 900.12(c)(4)(v)),

• add or substitute the term ''patient'' in place of references to ''women'' or ''woman'' (§§ 900.12(c)(4)(v) and (f)(1)),

• add the word ''audit'' to clarify that the use of certain terms applies to the medical outcomes audit (§ 900.12(f)(1)), and

• include an amendment changing the name of Healthcare Financing Administration to Centers for Medicare & Medicaid Services and updating the Center for Devices and Radiological Health (CDRH) office's name (§ 900.15(d)(1)).

IV. Legal Authority

The MQSA (Pub. L. 102–539) was enacted on October 27, 1992, and is codified under section 354 of the Public Health Service (PHS) Act (42 U.S.C. 263b). Under the MQSA, all mammography facilities, except facilities of the VA, must be accredited by an approved AB and certified by FDA (or an approved State certification agency) to provide mammography services (42 U.S.C. 263b(b)(1) and (d)(1)(iv)). FDA is making these amendments to the mammography regulations (set forth in part 900 (21 CFR part 900)) under section 354 of the PHS Act, and sections of the FD&C Act (sections 519, 537, and 704(e); 21 U.S.C. 360i, 360nn, and 374(e)).

V. Comments on the Proposed Rule and FDA's Responses

We received several sets of comments on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. We describe and respond to comments in sections A through Z of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number so that FDA's responses could be addressed by topic, instead of each comment addressed independently, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received or considered.

A. General Comments on the Proposed Rule

(Comment 1) FDA received many comments that express support for the MQSA proposed rule. Some comments express support for requiring density notification to patients and for establishing a national standard for such notification. Other comments respectively express support for the changes to the assessment categories, equipment quality control (QC), and requirements related to the provision of copies of mammograms. Some comments express support for the changes to the patient and provider notification in the event of compromised mammographic quality, which may represent a serious risk to human health, including the notification of nonphysician referring healthcare providers. Another comment compliments FDA on proposing amendments to the regulations, but recommends more frequent changes to respond promptly to new information.

(Response 1) FDA appreciates the public support for the rule. FDA notes that the notification requirement regarding breast tissue density will enhance communication between patients, interpreting physicians (IP), and referring providers about this important factor in the effectiveness of mammography, and ensure that required baseline information is consistent. FDA also concludes that the other amendments to the regulations (part 900), including the changes to the equipment QC, assessment categories, provision of copies of mammograms, and notification to nonphysician healthcare providers when necessary, will also contribute to improvement in the quality of mammography and of communication about mammography between patients, IPs, and providers. Regarding the recommendation for more frequent changes, FDA notes that it continues to engage with the National Mammography Quality Assurance Advisory Committee (NMQAAC) and the professional and patient mammography communities regarding the need for changes to the regulations, but the frequency of amendments to the regulations is based on public health need and Agency resources.

(Comment 2) Several comments express opposition to the proposed rule, including the following concerns: (1) that patients will not understand that dense tissue is a normal variant, and that the proposed breast density notification will increase their anxiety; (2) that breast cancer information to be given to a patient should be determined only by the patient's healthcare provider, or that the new requirement places a burden on the healthcare provider; (3) that all medical tests should be interpreted by clinicians with years of training who can identify the findings that require intervention; (4) that ultrasound rather than digital breast tomosynthesis (DBT) is the method to screen for cancers that are not mammographically visible; and (5) that there is no clinical recommendation to change patient management based on density or to perform additional ultrasound and magnetic resonance imaging (MRI) for screening dense breasts, and that current evidence contradicts the suggestion that supplemental screening based on breast density reduces breast cancer mortality. The latter comment also recommends that FDA's suggestion that additional imaging based on density alone may reduce breast cancer mortality should be deleted from the cost and benefit information of the rule.

(Response 2) FDA acknowledges the comments and responds according to the numbered topics identified in Comment 2:

(1–2) We note that breast tissue density is an important factor in mammography, both because of the masking effect of dense tissue, which limits the sensitivity of mammography (Refs. 9 to 11), and because density is an independent risk factor for the development of breast cancer (Refs. 12 to 15). FDA concludes that patients benefit from having information about their breast anatomy, and should be informed of their density so that the patient and their healthcare provider can make informed and shared decisions about the patient's healthcare. This rulemaking provides consistent language for communicating that information, as FDA concludes that there is also a benefit from obtaining baseline information in a consistent manner.

The requirement to notify patients about their density is a baseline standard and does not constrain a healthcare provider from further discussing density with the patient. FDA has determined that the benefit of informing patients of their density

outweighs both the burden on healthcare providers to provide density information and the risk of patient anxiety. FDA also notes that the Agency received many comments in support of the proposed rule and the breast density notification to patients. FDA also notes that 38 States have passed laws mandating notification of breast density, which may mitigate any potential burden on healthcare providers in those states (Ref. 8).

(3) The MQSA provides authority to FDA to ensure quality mammography, and FDA has determined that the initial and continuing qualification requirements for IPs in § 900.12(a)(1) are sufficient to ensure that mammograms, including density observations, are interpreted by personnel with adequate training to ensure quality mammography.

(4–5) FDA acknowledges there are conflicting comments about the utility of other imaging modalities besides DBT, such as ultrasound, for supplemental screening of women with dense breasts; however, this final rule does not specify any particular supplemental imaging modality or other particular clinical management of patients with dense breasts. FDA has not indicated any particular additional steps in a patient's care based only on the mammogram, as individual situations and risk factors vary. FDA does not agree that it is appropriate to require the lay summary to include a discussion of all possible breast imaging modalities that may be more effective for some patients than mammography, which would encompass a significant amount of information that may be overwhelming and difficult for patients to interpret (see also Responses 57 and 60). We believe that it is more appropriate for the healthcare provider to discuss this information with the patient and engage in shared clinical decision-making based on the patient's individual circumstances. In this final rule, to allow patients and their healthcare providers to make shared decisions appropriate for each patient, the notification to these patients in § 900.12(c)(2)(iv) simply states, in part, ''In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers,'' and advises the patient to discuss their individual situation with their provider (see also Response 62). FDA notes that there is conflicting evidence about the effect of supplemental screening on breast cancer mortality, including Chiu in 2010 (Ref. 16), which found that dense tissue was associated with increased mortality from breast cancer. Therefore, FDA disagrees with the assertion that additional imaging based on breast density is not relevant, or that the mortality information should be deleted from the economic cost and benefit analysis of the rule.

(Comment 3) A comment opposes more mammography regulation, and asserts:* that MQSA duplicates an American College of Radiology (ACR) program which ''certifies'' mammography facilities; that FDA dictating what IPs should say in their reports constitutes the practice of medicine; and that MQSA regulations are driving physicians out of mammography and limiting access. This comment recommends that FDA limit itself to its ''original mandate'' to ensure that mammography units produce quality images at a reasonable radiation dose.

(Response 3) FDA disagrees with the comment. The ACR does not certify mammography facilities. The MQSA and its implementing regulations distinguish between accreditation and certification (see 42 U.S.C. 263b(e) and (q); part 900, subparts A and C; see also Response 145). The ACR is one of several FDA-approved accreditation bodies. Accreditation, which mainly focuses on the quality of clinical images and phantom images, is one of the prerequisites for facility certification by FDA or a State certifying agency. FDA does not specify which assessment category an IP should assign to a mammogram because this is more appropriately left to the provider's interpretation in the course of clinical decision-making. However, FDA does provide for the specific phrasing of the final assessment statements, which is standardized in accordance with the MQSA (42 U.S.C. 263b(a)(3)(B)) to ensure clear consistent communication between patients, IPs, and referring healthcare providers. FDA does not track practice rates of IPs or other facility personnel, but is not aware of information showing a decrease in access to mammography services; according to MQSA national statistics (Ref. 17), from November 2003 to February 2022, there has been a 4 percent decrease in the total number of certified facilities across the United States but a 29 percent increase in the total number of mammograms performed. Therefore, FDA concludes that these amendments to the MQSA regulations are neither duplicative of the ACR program nor have the existing MQSA regulations had a negative impact on access to mammography.

B. Scope of the MQSA Regulations

(Comment 4) Several comments address the scope of the MQSA regulations, including comments that support the objectives of the proposed rule and/or provide the following recommendations: (1) FDA's proposal should remove xeromammography from the examples of mammographic modalities, which accompany the definition provided in proposed § 900.2(z), and replace it with full-field digital mammography (FFDM); (2) FDA should remove screen-film mammography from these examples of modalities; (3) comments that FDA should also add the example of DBT as a modality; (4) that mammography IPs should also be qualified in breast ultrasound; and (5) that FDA should consider requiring mammography facilities to meet additional quality standards, such as the ACR's Breast Imaging Centers of Excellence (BICOE) program or the American Cancer Society (ACS) National Accreditation Program for Breast Centers (NAPBC), in addition to MQSA certification requirements.

(Response 4) The scope of FDA's authority over mammography facilities is established in the MQSA, and, as described in the following and organized according to the numbered topics identified in Comment 4, FDA is adopting limited changes to this rule:

(1–3) The MQSA and its implementing regulations apply only to radiological equipment used in facilities to perform mammographic modalities, which do not include breast sonography or other non-mammographic modalities (42 U.S.C. 263b(a)(5) and (6), (b)(1) and (2)). However, FDA agrees that the modality of DBT has reached wide clinical use and should be listed as an example of a mammographic modality in this rule. Xeromammography is no longer in clinical use in the United States, and screen-film mammography is in limited use. Therefore, in this final rule, FDA is revising the examples of mammographic modalities to remove xeromammography, and to list screen-film mammography, FFDM, and DBT, all of which are currently in clinical use in the United States (see § 900.2(z) in this final rule). Other modalities are covered by the requirements of the FD&C Act, and may be subject to performance standards prescribed pursuant to section 534 (Electronic Product Radiation Control (EPRC)) of the FD&C Act.

(4) FDA disagrees with the recommendation to require mammography IPs to also be qualified in breast ultrasound. As noted, the MQSA does not provide for the establishment of requirements related to breast sonography for IPs, other personnel, or facilities.

(5) FDA notes that the ACR BICOE program covers other breast imaging modalities and interventions in addition to mammography, and the ACS NAPBC covers additional breast imaging as well as other aspects of clinical breast care. Therefore, these programs are not implemented within the scope of the MQSA regulations.

(Comment 5) Several comments recommend removing the exclusion of invasive interventions for biopsy or localization in § 900.2(aa)(1) so that they are included within the scope of the MQSA regulations. A separate comment recommends that post-procedure mammograms for marker placement should not be regulated under the MQSA.

(Response 5) FDA disagrees with these comments. The MQSA was enacted by Congress in 1992 due to evidence of poor quality in mammographic imaging in the United States at that time. However, since then, the implementation of the MQSA and the widespread adoption of digital imaging technologies and other technological and QC advances have contributed to quality improvement not only in screening and diagnostic mammography, but also in interventional mammography. The majority of personnel performing interventional mammography also perform non-interventional mammography and are therefore subject to the requirements of the MQSA. Currently, FDA is not aware of information showing significant quality problems with interventional mammography in the United States. At this time, FDA concludes that it is not necessary to introduce regulations covering interventional mammography.

Unlike the targeted images of a small portion of the breast that are typically performed during localization or intervention, a post-procedure mammogram typically includes the entire breast; may be performed using general mammography equipment rather than dedicated interventional equipment; and is often logged, reported, and charged as an independent examination, separate from the interventional procedure that precedes it. Therefore, FDA concludes that this post-procedure examination should continue to meet the quality standards mandated under the MQSA regulations. As discussed in Responses 32, 38, and 39, this final rule includes the assessment statement ''Post-Procedure Mammogram for Marker Placement,'' which may be appropriate for such mammograms (see § 900.12(c)(1)(iv)(G)).

(Comment 6) Several comments suggest that the MQSA regulations should be expanded to cover other imaging modalities in addition to mammography, including ultrasound and MRI.

(Response 6) The MQSA was passed by Congress in 1992 in response to evidence of poor quality in mammographic imaging in the United States at that time (42 U.S.C. 263b). As we noted in Response 4, the MQSA applies only to mammographic imaging. As such, the MQSA does not provide for the establishment of requirements related to breast sonography or MRI, and the MQSA regulations have not been amended to include such modalities.

(Comment 7) A comment recommends that medical offices be required to display posters depicting breast anatomy and to distribute literature regarding breast physical examination.

(Response 7) FDA disagrees with the comment. FDA notes that the shared clinical decision-making process generally takes place between the patient and their referring healthcare provider or other clinical healthcare provider, not with the interpreting physician at the mammography facility, and therefore does not agree that there is a need to require posters of breast anatomy at mammography facilities, although facilities may choose to display patient education resources. Referring healthcare providers who order mammography studies, and are not themselves the reviewing physicians of the clinical images at issue (see 42 U.S.C. 263b(a)(8)), are not generally subject to the requirements specified in the MQSA and its implementing regulations. Clinical healthcare providers may provide such patient education resources if they choose to do so, but this recommendation is outside the scope of this final rulemaking.

C. Repeated Failure To Achieve Accreditation

(Comment 8) Several comments express concerns with the number and type of accreditation failures after which an AB may not accept a facility's application for accreditation for 1 year. One comment recommends that this provision be revised to apply to a facility that has ''failed to become accredited after four consecutive failures''; another comment recommends that this be revised to apply to a facility which has ''failed to become accredited after four failed accreditation cycles''; and another comment recommends that this be revised to apply to a facility that has had ''three consecutive failures of accreditation granting cycles.'' Two of these comments also express concern over the effect of this provision on the timing of the AB's onsite visit to the facility to provide oversight and hands-on training.

(Response 8) FDA disagrees with these comments. The Agency believes that a facility that has failed to become accredited after three consecutive attempts should not be permitted to become accredited until it has implemented all necessary corrective actions and any other necessary changes, such as additional training or personnel changes, specific to the facility's individual situation (see § 900.4(a)(6)(ii) in this final rule). The Agency believes that the 1-year waiting period will allow the facility sufficient time to make these corrections. Regarding the terminology used for these failures, the Agency notes that the various FDA-approved ABs currently use different terms, such as ''deficiency'' and ''failure,'' for the initial failure to become accredited. Therefore, FDA concludes that the phrasing of the provision, ''If a facility has failed to become accredited after three consecutive attempts,'' is sufficiently clear and broad to apply to facilities accredited by any AB. Regarding the AB onsite visits to facilities, the various ABs currently have different policies for the timing of their onsite visits, each respectively approved by FDA. FDA notes that, upon publication of this final rule, the ABs can review and, if needed, revise their procedures to accommodate the change in the regulations, including to account for any procedures to address tracking the number of facility applications submitted to an AB, and submit their proposed policy changes to FDA for review and approval.

(Comment 9) Some comments recommend that facilities not be allowed to switch ABs in order to avoid this 1-year exclusion after three consecutive failed attempts at accreditation.

(Response 9) FDA agrees with this recommendation. Accordingly, we are revising § 900.4(a)(6)(ii) to state ''If a facility has failed to become accredited after three consecutive attempts, no AB shall accept an application for accreditation from the facility for a period of 1 year from the date of the most recent accreditation failure.''

(Comment 10) Some comments address the situation of a facility with more than one mammography unit, of which one unit fails to receive accreditation but one or more units receive accreditation. These comments recommend either that the facility be

permitted to continue to perform mammography with the remaining accredited unit(s), or that the facility's individual situation be evaluated by the AB to determine the appropriate course of action.

(Response 10) We appreciate the comment, but note that the commenter misunderstood the proposed amendment. The provision that was proposed for revision refers to overall facility accreditation (see § 900.4(a)(6)(ii) in both the proposed and final rule) as opposed to individual unit accreditation (see §§ 900.4(e) and 900.12(e)). FDA acknowledges that some reasons for the failure of a facility to receive accreditation, such as a mechanical deficiency in a mammography unit, may be limited to that particular unit, while other reasons for failure, such as poor patient positioning, may extend to the practice of mammography throughout the entire facility. The various FDA-approved ABs have policies to address the requirements for accreditation of a facility that has multiple mammography units. The ABs also have policies regarding the circumstances, including poor quality noted on accreditation images, which may prompt an AMR to assess the overall quality of mammography at a facility. FDA believes that if a facility fails three consecutive attempts to receive accreditation, it should be subject to a 1-year waiting period to allow the facility adequate time to address issues that have prevented accreditation (see also Response 8). FDA anticipates that the ABs may review their policies and procedures, and if needed, may decide to submit revised policies and procedures to FDA (see § 900.4(a)(8)) to conform to this provision of the final rule; if the ABs do so, the Agency will review and consider the ABs' proposals.

(Comment 11) A comment recommends that a facility under its third provisional certificate have all exams double-read by a qualified IP from an accredited and certified facility, until the applying facility either fails or receives accreditation.

(Response 11) FDA disagrees with adding this requirement to the regulations. Such increased oversight of facilities with provisional certificates is not appropriate in this circumstance, considering that there are existing regulations requiring corrective action. Depending on the specific circumstances of the failure, the applying facility's AB will either have required the facility to perform corrective action after the first two failures, or will first have performed an AMR to determine the extent and severity of the quality problems at the facility (see § 900.4(a)(1)(i)), and will have required corrective action (see §§ 900.4(a)(1)(ii) and 900.4(b)(3)). Corrective action is individualized by the AB for the specific facility, but often includes requirements for additional training for the facility personnel. Therefore, FDA concludes that the IP and other personnel will be sufficiently trained to correct the quality problems at the facility.

(Comment 12) A comment recommends clearer language about the facility's next steps, corrective action, ''necessary information,'' and the duration of effectiveness of a provisional certificate for a facility that has had a year-long waiting period after having failed to become accredited after three consecutive attempts. The same comment recommends clearer language about FDA's action if a facility fails accreditation for a third time, and also recommends that a facility be permanently ineligible to provide mammography services after a fourth failure.

(Response 12) Regarding improving clarity about the process for reapplying for accreditation, FDA disagrees with this comment. The process is subject to the policies and procedures of each AB, and the Agency notes that the necessary information as well as the steps to apply for accreditation are clearly specified by each AB's policies and procedures (see, *e.g.,* § 900.4(e) and (f)). We further note that the duration of effectiveness of a provisional certificate is already discussed in current § 900.11(b) and (c). Regarding the commenter's recommendation that a facility be ineligible to provide mammography services after a fourth failure, FDA concludes that a facility that has performed all required corrective action may reapply for accreditation, but notes that, in accordance with AB policies, an AB may take into account the facility's entire history and practice of mammography, such as a lack of improvement after multiple corrective actions, in considering a decision to suspend or revoke the facility's accreditation, or to revoke its application for accreditation (see § 900.4(a) and (b)). Also, the AB must notify FDA if it believes that a facility's practice of mammography may pose a serious risk to human health (see § 900.4(a)(2)). Likewise, the Agency may take into account the facility's entire history in determining that its practice poses a serious risk to human health and in considering the suspension or revocation of a facility's certificate (see § 900.14). Therefore, FDA concludes that a facility whose practice warrants such a determination will be identified, and appropriate accreditation and/or certificate actions will be taken. Finally, as noted in Responses 8 and 10, if the ABs review their policies and procedures in light of this provision of the final rule and decide to submit revised policies and procedures to FDA (see § 900.4(a)(8)), the Agency will review and consider those policies and procedures.

D. Retention and Release of Personnel Records

(Comment 13) Several comments were submitted that recommend specifying the amount of time that a facility must retain personnel records for employees that are no longer at that facility. Some comments recommend that facilities only be required to keep the records for former employees from the time of one inspection to the time of the next annual inspection. Another comment recommends that facilities only be required to give employees their records at the time of the employees' departure. Other comments recommend that facilities be required to keep personnel records for former employees for 24 months following the departure of that employee.

(Response 13) FDA agrees that a minimum length of time should be included in the amendments to the regulations for the personnel records retention requirement. We note that previous employees may need access to these personnel records to document their MQSA qualifications to permit them to provide mammography services at other facilities. Accordingly, we conclude that former employees should have an opportunity to obtain their personnel records for a time period beyond the immediate date of their departure from a facility. After considering the comments on this requirement, we are revising and finalizing the provision as follows: ''Records of personnel no longer employed by the facility must be maintained for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months'' (see § 900.12(a)(4) in this final rule). FDA has made this change to the codified language to clarify that the records must be available during an inspection that can occur at any point during the 24 months after which an employee departs, which better aligns with the records retention requirement and is distinct from any FDA determination regarding compliance with the MQSA and its implementing regulations that would

otherwise occur following the next annual inspection after the employee departs. FDA is also revising the provision to distinguish and clarify the requirements for providing such records to current and former employees, as follows: ''The facility shall provide copies of these personnel records to current interpreting physicians (IPs), radiologic technologists, and medical physicists upon their request. Facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.''

(Comment 14) Rather than providing records after an employee leaves, a comment recommends that facilities should require a qualifications package for each employee that would only be retained until after the first inspection following the hiring of that employee, at which point the package should be given to the employee to retain, and any continuing experience or other information would be accumulated and maintained from the time that the qualifications package is given to the employee.

(Response 14) FDA disagrees with this comment. Personnel qualifications under § 900.12(a) include both initial and continuing requirements, and both components are reviewed at the time of inspection (Ref. 18). The personnel record keeping requirements apply to facilities, not individual personnel (see 42 U.S.C. 263b(d)(1)(A)(ii)(III), (B)(ii)(II), and (g)(1)(C), and § 900.12(a)(4)). Therefore, each facility is required to document the qualifications of its personnel. Also, FDA is concerned that the comment's recommended changes would not be as effective as the current system in maintaining the necessary documentation of qualification of a facility's personnel.

(Comment 15) A comment recommends that FDA specify a penalty for facilities that do not adhere to the personnel records requirement.

(Response 15) FDA agrees with this comment. A facility that does not comply with the personnel records retention requirement (see § 900.12(a)(4) in this final rule) may receive a citation at the time that this failure is identified at inspection, in a manner similar to other comparable violations (Ref. 18). The totality and severity of violations identified at inspection determine the consequences for the facility.

(Comment 16) A comment recommends that facilities should only need to provide personnel records to former employees if the employee submits the request in written format.

(Response 16) FDA disagrees with this recommendation. FDA concludes that requiring requests from former employees for their personnel records to be transmitted in writing may be overly burdensome to both facilities and former employees because it may delay how quickly a facility would receive the request, and may reduce access to mammography by delaying how quickly those records could be provided to facilities evaluating the qualifications of new personnel. FDA believes that minimizing barriers to the provision of qualification records to former employees will facilitate the hiring of these personnel at other facilities, thus preserving patient access to mammography services.

(Comment 17) A comment recommends that facilities give personnel records to personnel when the facility ceases performing mammography, and it also asks for clarification as to whether the phrase ''ceases to perform mammography'' refers to the facility or to specific personnel.

(Response 17) The final rule states that ''Before a facility closes or ceases to perform mammography services, it must make arrangements for access by current and former personnel to their MQSA records,'' and that this may be accomplished by either ''the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for no less than 24 months from the date of facility closure or cessation of mammography services'' (see § 900.12(a)(4)). FDA believes that these two pathways provide adequate access for personnel to their MQSA records. The primary reason that personnel may require access to their qualification records is that they are continuing to practice mammography at other facilities. Therefore, the clause ''Before a facility closes or ceases to provide mammography services'' (see § 900.12(a)(4) in this final rule) refers to the closure or cessation of mammography services of a facility and not to the cessation of specific personnel from practicing mammography.

(Comment 18) A comment requests that FDA provide guidance on how to demonstrate compliance with the requirement to provide access for personnel to their MQSA records when a facility closes or ceases mammography services.

(Response 18) The Agency believes that the current regulations, and the regulations being revised at § 900.12(a)(4) in this final rule, are clear on the requirements regarding personnel records for facilities that close or cease to provide mammography services. Facilities that close or cease to perform mammography services should inform their AB, which will assist them in complying with record retention obligations and other applicable MQSA requirements. (Ref. 19.)

E. Digital Accessories

(Comment 19) Several comments request that FDA provide additional clarification of the definition of a digital accessory component, or ask for clarity on whether specific equipment, such as display monitors, are included in this category.

(Response 19) FDA defines an ''accessory'' of a device as ''A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices'' (Ref. 20). Because a device accessory is a ''device,'' we believe the broader term ''devices'' is simpler and allows for a clearer understanding of the mammography regulations. In this final rule, we are revising § 900.12(b)(2)(i) for clarity, to state that ''All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type and intended use.'' This applies to devices used in the acquisition, processing, or display of digital mammographic images. For example, a display device used in the interpretation of digital mammographic images generally needs to have 510(k) clearance prior to being used in a mammographic facility. Not all equipment needs clearance or approval; for example, some devices, such as medical image storage devices, may be exempted from premarket notification requirements. (It is important to consult the appropriate classification regulation to determine the premarket authorization requirements.)

(Comment 20) Several comments recommend changing the effective date for the digital accessory component requirements from 18 months to 24 months.

(Response 20) FDA disagrees with the recommendation to extend the effective date to 24 months after publication of this final rule. FDA considers 18 months to be a reasonable amount of time for facilities to achieve compliance with this requirement, based on both previous experience with the 18-month effective date specified in the 1997 MQSA final rule (62 FR 55852, October

28, 1997) and the need for timely effectiveness of this rule.

(Comment 21) Other comments recommend that, for QC testing of digital accessories, in addition to the use of QC procedures in the manufacturer's manual, the proposed rule should add an option to use the ACR QC manual.

(Response 21) Alternative requirements for § 900.12 quality standards are addressed in § 900.18. The current ''ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems'' has been approved as applicable to any facility as alternative standard #24 (Ref. 21; see also § 900.18(f)). The use of approved alternative standards such as the ACR QC manual as they relate to digital accessories remains acceptable; however, since the ACR manual may undergo future revisions, and a revision would have to undergo FDA review to determine whether it is at least as effective in ensuring quality mammography as the standard it proposes to replace, the current ACR manual is not specified in the codified section of the final rule.

(Comment 22) A comment expresses concern that a facility using displays that are not specific for mammography or for a use that could include mammography would be in violation. Another comment suggests that, if a manufacturer QC procedure exists, there is no need for FDA premarket authorization of displays, and continues that there is no need for FDA premarket authorization for equipment since there are alternative standards for QC from the ACR. A comment also asserts that the process by which FDA clears or approves displays is not transparent.

(Response 22) These comments tend to confuse two separate processes: (1) the premarket approval or clearance of a medical device as described in 21 CFR 807.81 and (2) the MQSA requirements for mammography facilities under 42 U.S.C. 263b and the implementing regulations under part 900. Medical devices are subject to FDA's medical device requirements, which may include premarket authorization. Mammography equipment must also meet MQSA regulatory requirements that govern its use in a mammography facility.

FDA premarket authorization of a display intended for use in interpreting mammography images is a premarket device requirement; however, after this final rule becomes effective, any applicable premarket authorization requirements will also be required under the MQSA quality standards for use of the display for interpreting mammography images (see § 900.12(b)(2)(i) in this final rule). Therefore, FDA agrees with the comment that a facility interpreting mammograms using a display that has not met the applicable FDA premarket authorization requirements for use in interpreting mammography images would generally be in violation of the MQSA quality standards regulations.

The QC tests for a display are another MQSA quality standard required for use of that display for mammography interpretation (see § 900.12(e)(6)), but the existence of QC tests for a display is generally not sufficient to satisfy all FDA premarket regulatory requirements that may apply to the device. Likewise, the existence of a QC program for other mammography equipment does not generally satisfy all the premarket regulatory requirements applicable to that equipment. Regarding the comment that states there are QC procedures available from ACR, we also note that facilities that adopt the ACR QC manual for the QC of their FFDM or DBT system may not limit the use of the manual to a single piece of equipment or accessory, such as a display, while following a different QC program (such as the manufacturer's QC manual) for the mammography unit (Refs. 21 and 22), and we reiterate that the existence of a QC program does not necessarily reflect that any applicable FDA premarket authorization requirements are being met.

Regarding the comment on the clarity of FDA premarket review process for mammography displays, the premarket requirements for displays that are intended to be used in interpreting mammography images, among others, are discussed in 21 CFR 892.2050 and FDA's guidance ''Display Devices for Diagnostic Radiology'' (Ref. 23).

(Comment 23) A comment states that the requirement that mammograms submitted for interpretation be ''presented in the mammographic modality'' in which they were originally produced is unclear, and suggests that mammograms are being read on a device not intended for mammography. The comment also recommends including a statement to caution facilities that they should be aware of potential compatibility issues in their imaging/reading chain.

(Response 23) The requirement that mammograms be presented for interpretation in the mammographic modality in which they were originally produced means, for example, that screen-film mammograms must be presented for interpretation as the original hardcopy films, and not digitized or scanned. FDA does not agree that this requirement would reasonably be interpreted to mean that mammograms are being read on equipment not intended for mammography. FDA notes that all equipment used for mammography must be specifically designed for mammography (see § 900.12(b)(2) in this final rule) and that all devices used in mammography (including displays, as discussed in Responses 19 and 22) must have met the applicable FDA premarket authorization requirements for medical devices of that type and intended use (see § 900.12(b)(2)(i) in this final rule). FDA agrees that facilities are responsible for ensuring that any equipment they use in the acquisition, processing, interpretation, retention, and retrieval of mammographic images be compatible, in order to facilitate mammography practice and to allow compliance with the record retention, transfer, and release provisions in § 900.12(c)(4) of this final rule. The Agency does not believe it is necessary to include a cautionary statement in the final rule, as facilities in the course of their practice of mammography will readily be able to determine whether their equipment is interoperable.

F. Facility Identification Information in Mammography Report and Lay Summary

(Comment 24) A comment requests clarification, in the case of a facility that is associated with a centralized entity that sends reports and summaries, as to whether the centralized entity may be the only name on the report or summary, whether an abbreviated name for the actual facility is acceptable, and whether an alias (*e.g.,* ''Doing Business As'' or DBA) is required to appear on the report. The commenter also requests clarification of the required timeframe for a facility to report a name change.

(Response 24) FDA distinguishes each mammography facility based on its physical location (see 42 U.S.C. 263b(a)(3) and § 900.12(c)(1)(ii) in this final rule). Healthcare networks that offer mammography services at several locations are accredited and certified as several separate facilities. The name recognized by FDA for a facility is the name under which the facility is accredited by its AB (see § 900.11(b)). Therefore, the facility identification information in the report to the healthcare provider (see § 900.12(c)(1)(ii) in this final rule) and the lay summary sent to the patient (see § 900.12(c)(2) in this final rule) must be unique to the actual facility where the

mammogram was performed, and must include the name under which the facility is accredited and certified. A change to a facility's name must be submitted to the facility's AB, and is subsequently conveyed to FDA by the AB (see § 900.11(b)); therefore, the timeframe for reporting a name change, as well as the acceptability of an alias or DBA, are governed by the policies of the AB.

(Comment 25) A comment recommends that FDA specify whether the report identification information is required for a ''consult report.''

(Response 25) The commenter's reference to a ''consult report'' is not clear. Typically, a mammogram will be interpreted only once, and will have only a single report and a single lay summary. In some cases, a mammogram that has already been interpreted and for which a report and lay summary have been issued is subsequently presented to another IP for a repeat interpretation or ''second opinion.'' By referencing determinations made by an ''outside consultant,'' the commenter may either be referring to a later IP rendering such an additional opinion on an examination that has already been interpreted, or may be referring to an IP who is a contractor to a facility (rather than a facility employee) rendering the initial or sole interpretation. If the comment refers to the reinterpretation of a previously interpreted mammogram, the second (or subsequent) IP must also meet the existing personnel requirements of § 900.12(a)(1), and must separately comply with the reporting requirements of § 900.12(c) in this final rule. To help distinguish them from the original interpretation, we recommend that a second (or subsequent) report and lay summary be identified as a second opinion or similar term. If the comment refers to a report rendered by an IP who is a contractor or consultant to the facility rather than a facility employee, that IP must also meet all personnel requirements, and the report and lay summary must meet all reporting requirements.

(Comment 26) Several comments address the required identification information in the lay summary. A comment asserts that most facilities already provide facility identification in the lay summary. Another comment recommends that the patient name and the facility information be required in the lay summary. A separate comment recommends that the summary include separately both the contact information of the facility or business where a patient can request images and records, and the actual physical location where the mammography services were provided. Another comment recommends that FDA not specify the information that is required ''at a minimum,'' but rather specify all required information, including the facility telephone number, email address, and instructions for clear communication.

(Response 26) FDA agrees that there have been situations in which the facility information in the lay summary was inadequate. FDA concludes that the expanded requirements in § 900.12(c)(2) of the final rule will enhance communication between the facility, the patient, and the referring provider, and lead to improved patient care. Because, as noted in Response 24, FDA identifies each facility by its unique location (see § 900.12(a)(1), in both the proposed and final rule), the location of the facility where the mammogram was performed must be included in the lay summary. In response to the comment recommending that a facility's parent company information be included in the header, FDA does not agree that such additional information should be required because FDA identifies each facility by its unique location and not by any affiliation with a network or company. However, a facility may choose to include additional information about a healthcare network, affiliated site, or records storage site. In addition, FDA agrees with the recommendation that the facility telephone number be included with the lay summary, and notes that § 900.12(c)(2) of both the proposed and final rule include this requirement. Because in FDA's experience, some facilities do not have email addresses, and some others communicate through patient portals, FDA disagrees with the recommendation to require that the lay summary include an email address or instructions for clear communication between the patient and the facility. FDA notes that facilities may choose to include this additional contact information.

(Comment 27) A comment recommends that the lay summary be required to include the name of the IP, so that patients will know who is involved with their care, and if dissatisfied, can request a different IP.

(Response 27) FDA does not believe it is necessary to require the name of the IP as part of the lay summary. A facility may choose to include this information, but it is not required. The Agency notes that the lay summary is prepared after the examination has been interpreted, so adding the name of the IP to the lay summary will not intervene early enough for the patient to request a different IP. A patient who prefers a particular IP would have to discuss such a request with the facility staff before the mammogram is interpreted. After interpretation by the IP, FDA notes that the name of the IP is included in the report to the referring provider, per § 900.12(c)(1)(iii), and the patient can request the name either from the facility or from the referring provider.

G. Final and Incomplete Assessments and Lay Summaries

(Comment 28) A comment recommends that FDA clarify the limits of the required assessment language for each mammographic assessment category, and recommends that the rule preserve the concept that the assessment statement is required, while the explanatory language is not required to be included in the mammography report.

(Response 28) For each assessment category, the required assessment statement is only the word or phrase in quotation marks (see § 900.12(c)(iv) in this final rule). As in the existing regulations, each assessment statement, identified in quotation marks, is followed by explanatory language, which is not in quotation marks; this explanatory language not in quotation marks is intended to provide an explanation of the assessment category in order to promote its consistent use, but it is not part of the assessment statement, and is not required to be included in the report to the referring healthcare provider nor in the lay summary to the patient. This format of an assessment statement in quotation marks followed by explanatory language outside the quotation marks was also used in the existing regulations, and FDA is not aware of significant confusion caused by this format. In both the proposed and final rule, § 900.12(c)(1)(iv)(A) through (G), the explanatory language is distinguished from the assessment statement by the closing quotation mark at the end of the assessment. For added clarity, in this final rule we are revising § 900.12(c)(1)(iv) to add the parenthetical clarification, ''the assessment statement is only the word or phrase within the quotation marks.'' We are also revising § 900.12(c)(1)(iv) to replace the colon with a period within the quotation marks surrounding each assessment statement, to further clarify the distinction between the required statement and its explanatory language.

(Comment 29) A comment asserts that the negative and benign assessment categories are functionally equivalent and recommends combining them.

(Response 29) FDA disagrees with this comment. Although we acknowledge

that in most instances there may be no difference in clinical management between patients with negative mammograms and those whose mammograms show benign findings, the Agency notes that IPs often distinguish between these examinations and identify benign findings if they are present; therefore, we conclude that the negative and benign assessment categories should remain separate.

(Comment 30) A comment stated that the new ''Benign'' phrasing would be confusing to patients if sent to them. Another comment recommends that the verbiage explaining the term ''Benign'' not be required to be in the report.

(Response 30) FDA disagrees with the comment that the ''Benign'' phrasing would be confusing to patients. We note that the explanatory language following the word ''Benign'' in § 900.12(c)(1)(iv)(B) in this final rule is not part of the assessment statement. It is intended only to explain the category to IPs and other facility personnel, and is not required to be included in the report to the referring provider nor in the lay summary to the patient; therefore, patients are unlikely to be presented with such phrasing. We further note that even the word ''Benign'' need not be stated to the patient; a patient summary in lay terms of either a negative or a benign report might say, for example, ''Your mammogram is normal,'' ''Your mammogram shows no sign of cancer,'' or similar phrasing.

(Comment 31) A comment recommends that, in the parenthetical statement ''if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be explained'' (in proposed § 900.12(c)(1)(iv)(B)), the word ''explained'' should be revised to ''documented.''

(Response 31) FDA agrees in part with the comment. The parenthetical statement in the explanation of the benign assessment category is intended to mirror the existing parenthetical statement in the explanation of the negative assessment category (in § 900.12(c)(1)(iv)(A)), ''if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained.'' However, FDA agrees with the commenter that the IP may not always be able to explain the clinical finding or symptom in a patient with a negative or benign mammogram. Furthermore, the IP may have clinical information from a patient history form or interview that is not yet known to the referring healthcare provider, and is therefore not addressed by the subsequent requirement in proposed § 900.12(c)(1)(vii) that ''All clinical questions raised by the referring healthcare provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.'' FDA believes that this pertinent clinical information should be documented and, if possible, explained or otherwise addressed. Therefore, the Agency concludes that these parenthetical statements should be retained, with revision as suggested, for the negative assessment category (see § 900.12(c)(1)(iv)(A)) and for the benign assessment category (see § 900.12(c)(1)(iv)(B)). As such, FDA is revising the parenthetical language in this final rule for the negative and benign categories, respectively, to state that ''if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed,'' and ''if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed.''

(Comment 32) A comment requests confirmation that the new assessment categories are part of the alternative standard approved in 2003. Another comment requests confirmation that the ''FDA-approved'' equivalent wording for assessment categories is still permitted, and asserts that IPs should have the option to report equivalent language rather than the assessment statements in the regulations.

(Response 32) The new assessment statement ''Post-Procedure Mammogram for Marker Placement'' (§ 900.12(c)(1)(iv)(G)) is identical to alternative standard #12 approved by FDA in 2003 (Ref. 24). The new assessment statements ''Incomplete: Need Additional Imaging Evaluation'' (§ 900.12(c)(1)(v)(A)) and ''Incomplete: Need Prior Mammograms for Comparison'' (§ 900.12(c)(1)(v)(B)) are derived from alternative standard #11 approved by FDA in 2003 (Ref. 25). The statements ''Incomplete: Need Additional Imaging Evaluation'' and ''Incomplete: Need Prior Mammograms for Comparison'' represent the division of the single assessment statement in alternative standard #11 into two new assessment statements. These statements reflect FDA's recognition that some mammograms require comparison for interpretation, while some mammograms require additional imaging to reach a final interpretation.

The only authorized assessment statements are those in the quality standards and the approved alternative standards (Refs. 22 and 24; see also §§ 900.12(c)(1)(iv) and 900.18). In addition, as described in the MQSA Policy Guidance Help System (PGHS), FDA has acknowledged that some closely worded variations of the approved assessment statements may generally be acceptable where the particular wording does not change the meaning of the category (Ref. 26).

(Comment 33) A comment expresses concern that the reporting requirements, which seemingly would allow for an automated process of an IP selecting prepared comments that match the assessment categories, do not include an assessment statement or comment for patients with a history of breast cancer surgery who are subsequently undergoing routine screening.

(Response 33) Although FDA places requirements on the wording of the assessment statement used to describe the assessment category selected by the IP to promote clarity of communication between the IP and the referring clinical healthcare provider, we anticipate that the mammography report may include additional information about the findings of the examination, before the concluding assessment statement. FDA agrees that, after an IP examines the images, the IP may select prepared statements that in the IP's judgment accurately describe the findings of the examination, and likewise may select the final assessment from a prepared list of the approved assessment statements. The Agency anticipates that there will be some mammograms whose findings necessitate additional nonstandard statements within the report, but the report must conclude with one of the standard approved assessment statements listed in § 900.12(c)(1)(iv)(A) through (G). As applicable to the commenter's example, the patient's history of cancer and prior surgery, and any relevant post-surgical findings on the images, may be described in the report, but it must conclude with a final assessment chosen from the approved statements; for example, ''Benign'' (see § 900.12(c)(1)(iv)(B)) or ''Suspicious'' (see § 900.12(c)(1)(iv)(D)). The Agency does not believe it is necessary to add a unique assessment statement for patients with the history described by the commenter, as the statements listed in § 900.12(c)(1)(iv)(A) through (G) are adequate to encompass patients who have previously had breast cancer and those who have had surgery, whether for cancer or other reasons.

(Comment 34) A comment mentions the potential limitations of a mammogram when a patient either cannot cooperate with or cannot understand instructions, and recommends that FDA add assessment categories that reflect these limitations,

including ''Benign with technical limitation'' and ''Normal with technical limitation.'' Similarly, another comment mentions the limitation of dense breast tissue and recommends that FDA add an assessment category for ''Normal but dense.''

(Response 34) FDA agrees that some mammograms have technical limitations, but concludes that the limitations should be documented elsewhere in the report, not in the assessment statement. For clarity, the assessment statement should represent only the IP's final conclusion about the results of the examination. The limitation of breast density is addressed elsewhere in this final rule (see § 900.12(c)(1)(vi)(A) through (D)). In particular, the limitations conferred by dense tissue must be stated elsewhere in the report, using the language in § 900.12(c)(1)(vi)(C) of the final rule, ''The breasts are heterogeneously dense, which may obscure small masses,'' or § 900.12(c)(1)(vi)(D) of the final rule, ''The breasts are extremely dense, which lowers the sensitivity of mammography.''

(Comment 35) Several comments address the assessment category ''Suspicious,'' which the commenters erroneously refer to as a numerical category 4. These comments recommend that the use of alphanumeric subcategories 4a, 4b, and 4c be allowed, be encouraged, or be considered a legitimate option.

(Response 35) FDA disagrees with the recommendations to permit or encourage the use of alphanumeric subcategories instead of the assessment statement ''Suspicious.'' All the required assessment statements under the MQSA quality standards are words or phrases, not numbers. Thus, the assessment statements are not identical to the numerical codes derived from ACR's Breast Imaging—Reporting and Data System (BI–RADS) (Refs. 26 and 27). BI–RADS is a practice guideline published by a professional society (the ACR), and is not associated with the MQSA quality standard requirements. While a numeric or alphanumeric BI–RADS assessment code in addition to the assessment statement may be used, one of the overall final assessment of findings statements as described in § 900.12(c)(1)(iv) of this final rule must appear in the report.

For example, in BI–RADS, category 4 (Suspicious) offers optional subcategories a through c, and phrases associated with each letter (4a: ''Low suspicion for malignancy,'' 4b: ''Moderate suspicion for malignancy,'' and 4c: ''High suspicion for malignancy''), to further refine the level of suspicion (Ref. 28). However, for any mammogram that would receive an ACR BI–RADS code of either 4, 4a, 4b, or 4c, the assessment statement required under the MQSA quality standards is not a number or a letter, but the word ''Suspicious.'' Additionally, the phrase associated with each ACR BI–RADS code 4a through 4c is not an approved alternative standard for use as an assessment statement; while the final rule does not prohibit such a statement from being included in the report, the overall final assessment statement, ''Suspicious,'' would be the appropriate statement to include as the final assessment category of the mammogram (Ref. 29).

(Comment 36) A comment recommends that FDA provide examples of when referral of a self-referred patient to a healthcare provider is mammographically indicated.

(Response 36) The proposed § 900.12(c)(2)(ii) stated that ''Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when mammographically or clinically indicated.'' FDA believes that such referral is indicated when the mammographic findings warrant followup imaging or intervention sooner than at a routine screening interval. Therefore, for patients who do not have a healthcare provider and whose mammogram results are either probably benign, suspicious, or highly suggestive of malignancy, referral to a provider is generally mammographically indicated. For clarity, FDA is revising this provision to state, ''Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated, which shall include when such patients' mammogram assessment is either probably benign, suspicious, or highly suggestive of malignancy'' (see § 900.12(c)(2)(ii) in this final rule).

(Comment 37) A comment recommends that the lay summary inform the patient if risk factors such as density, pain, calcifications, discharge, and other items are identified on the mammogram.

(Response 37) FDA does not believe it is necessary to require this information in the lay summary. The facility is required to send the patient a summary of the mammography report written in lay terms (see § 900.12(c)(2) in this final rule). This final rule adds breast density notification language to the lay summary requirement, but it does not require that the lay summary mention patient symptoms or individual mammographic findings. FDA does not believe that it is appropriate to require specific language for the wide range of breast symptoms and mammographic findings that may be identified. For example, some of the items mentioned in the comment, such as pain and discharge, cannot be identified on a mammogram. The regulations require that the mammography report to the provider address findings, clinical questions raised by the referring healthcare provider, and recommendations for additional actions, if any, (see §§ 900.12(c)(1)(iv)(A) and (B) and (vii) in this final rule). Some findings or symptoms may be present but not clinically significant. The referring healthcare provider, who receives the mammography report and is also familiar with the patient's history and physical findings, is best positioned to discuss the case with the patient.

(Comment 38) Several comments address the proposed final assessment category ''Post Procedure Mammograms for Marker Placement.'' A comment asserts that the addition of an assessment category for a post-procedure mammogram is unnecessary. Another comment asserts that the post-procedure mammogram is ''bundled into'' the interventional procedure and does not receive an assessment. A comment requests clarification on whether a mammogram documenting a biopsy clip or marker requires documentation.

(Response 38) The assessment statement ''Post Procedure Mammograms for Marker Placement'' was approved as alternative standard #12 on September 17, 2003 (Ref. 24), under the mechanism described in current § 900.18 for the approval of alternatives to the MQSA quality standards in § 900.12. Since its approval in 2003, it has been available and acceptable for use as a final assessment statement. In this final rule, § 900.12(c)(1)(iv)(G), FDA is adding the nearly identical assessment statement ''Post-Procedure Mammogram for Marker Placement'' to the implementing regulations. The situations in which this assessment should be given to any particular mammogram are more appropriate for the IP to determine in the course of clinical decision-making. As FDA described in approval of the alternative standard, if a facility makes the post-procedure examination part of the interventional procedure instead of a separately charged examination, then the examination is not subject to the MQSA quality standard requirement and need not receive an assessment (Ref. 24). Nor would it require any report separate from the report of the

interventional procedure. However, when the post-procedure mammogram is logged or charged separately from the interventional procedure, this mammogram is a separate examination and requires a separate report.

This ''Post-Procedure'' assessment category is useful to distinguish examinations that simply document the localization of a known abnormality or a known marker without contributing new diagnostic information, so that these examinations are not misconstrued as showing new or additional abnormalities. The availability of a post-procedure assessment category also helps maintain the accuracy of the medical outcomes audit required under § 900.12(f). The audit requires followup for positive mammograms, defined in existing § 900.2(mm) as mammograms receiving assessments of either ''Suspicious'' or ''Highly Suggestive of Malignancy,'' but a post-procedure mammogram of a patient with a previously identified abnormality is not intended to be counted as a new positive result; this assessment category helps facilities to distinguish and exclude post-procedure mammograms from the audit.

(Comment 39) Two comments object to FDA's mention of a ''localization needle'' in the explanation of one potential use for this ''Post-Procedure Mammogram for Marker Placement'' final assessment, since spatial localization may not always be performed with a needle, and recommends revising this explanation to ''localization device'' or ''localization marker.'' Another comment asserts that a marker may not always deploy and recommends changing the wording of the assessment statement to ''Post procedure mammogram.''

(Response 39) FDA agrees that some localization devices are not needles, and is clarifying our explanation of the assessment category as follows: this category is primarily used for a mammogram performed following a biopsy to confirm the deployment and position of a breast tissue marker. The other use of this final assessment category is for a mammogram performed to document the position of a localization needle or other marker. During preoperative localization, a needle or other temporary marker may be positioned to direct subsequent surgery for a nonpalpable lesion seen on earlier mammography. The post-procedure mammogram is performed as a guide to identify the suspicious site for the surgeon who will biopsy or excise the lesion and remove the needle or marker.

The post-procedure mammogram is typically performed in an attempt to localize a device, such as a needle or other tissue marker, or to determine whether the device has deployed. FDA concludes that this intention is accurately captured by the phrasing ''Post-Procedure Mammogram for Marker Placement,'' even in cases in which the mammogram reveals that a marker failed to deploy. FDA notes that all mammographic views obtained in a single examination are typically referred to collectively as a ''mammogram,'' and therefore agrees in part with the comment that recommends changing the wording of the assessment statement to the singular ''Post procedure mammogram.'' Accordingly, we are revising the wording of the assessment statement to the singular ''Post-Procedure Mammogram for Marker Placement'' (see § 900.12(c)(1)(iv)(G) in this final rule), in addition to clarifying the description as noted.

(Comment 40) One comment asserts that a lay-language summary to the patient should not be required for a mammogram performed for marker placement, because the mammogram is performed for localization rather than for diagnosis, and receiving a lay summary of such an examination may confuse the patient.

(Response 40) As discussed in Response 38, we have explained that if a facility makes the post-procedure mammogram a separately logged or charged examination rather than part of the interventional procedure, the mammogram is subject to all MQSA quality standard requirements, including a report to the referring healthcare provider and a summary of the report in lay language to the patient. The lay summary must be specific to the examination and report; for example, if the assessment statement in a report states that an examination was a post-procedure mammogram for marker placement, then the lay summary of that report should likewise mention the procedure or the marker placement, but it would not be appropriate to state that the mammogram results were abnormal, worrisome, suspicious for cancer, etc. FDA believes that a lay summary limited to discussing the fact that the mammogram was performed for localization after a procedure will not confuse a patient who has just undergone a procedure.

(Comment 41) Several comments recommend that FDA revise the assessment statement ''Incomplete: Need prior mammograms for comparison'' (proposed § 900.12(c)(1)(v)(B)) to replace ''mammograms'' with ''breast imaging'' or ''breast examinations,'' to include other imaging modalities such as breast ultrasound.

(Response 41) FDA disagrees with this recommendation. The Agency concludes that extending the assessment statement ''Incomplete: Need prior mammograms for comparison'' to a comparison with other breast imaging modalities, which may have been performed at multiple different imaging facilities and centers, could impose delays in obtaining those prior examinations and issuing the final interpretation of the mammogram. As addressed in Response 4, the MQSA and FDA's implementing regulations apply specifically to mammography facilities, so facilities where a patient's prior mammograms were performed would have retained those examinations, pursuant to the MQSA record retention requirement (see § 900.12(c)(4)(i) in this final rule), and would presumably respond to the patient's request to transfer them or release copies of their records, pursuant to the MQSA record release requirements (see § 900.12(c)(4)(ii) and (iii) in this final rule). In contrast, other imaging centers not subject to the MQSA quality standards are not required to release prior non-mammography imaging within these regulatory deadlines. Additionally, other imaging modalities may not provide the type of information that is directly comparable to the mammogram.

(Comment 42) A comment requests confirmation that an Incomplete assessment statement, which the commenter cites as ''Category 0: Incomplete—need additional imaging evaluation and/or comparison with prior examination(s),'' remains acceptable. Similarly, another comment recommends that FDA allow facilities to choose whether to separate the two Incomplete assessment categories or to keep them grouped together.

(Response 42) The first commenter's citation of the assessment statement is incorrect on two points. As we noted in Response 35, all approved assessment statements under the MQSA quality standards are words or phrases, not numeric or alphanumeric codes, so the numeral zero is not required as part of the assessment. Also, the Incomplete assessment statement approved by FDA in 2003 as alternative standard #11 does not refer to ''prior examinations,'' but to ''prior mammograms.'' Therefore, the phrasing cited by the first commenter is not acceptable. However, we note that even after the introduction of the two Incomplete assessment statements in this final rule, alternative standard #11 remains in effect, such that the

combined assessment statement ''Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison'' may also be used. Therefore, FDA agrees with the second commenter that a facility may choose either to use one of the separate Incomplete assessment statements that appear in this final rule (see § 900.12(c)(1)(v)(A) and (B)), or to use the combined statement as found in alternative standard #11, which remains an approved alternative standard.

(Comment 43) A comment recommends that FDA expand and clarify its justification of the assessment category ''Incomplete: Need prior mammograms for comparison'' with a more evidence-based justification addressing the value of the comparison of a mammogram with prior mammograms. The proposed rule (under section V.E.3 of the Supplemental Materials) includes the statement, ''Comparison to previous examinations is sometimes required to make a final assessment.'' However, the comment recommends that FDA instead justify the value of comparison mammograms by using the statement, ''Evidence shows that comparison with a single prior exam, and more so with multiple prior examinations, improves accuracy, including a reduction in the recall rate and an improvement in sensitivity and predictive value.''

(Response 43) The reference cited by the commenter (Ref. 30) demonstrates that comparison to two or more prior exams reduces the recall rate, and increases the cancer detection rate and a positive predictive value (PPV) known as PPV1. Although comparison to previous examinations is valuable, FDA does not believe that the recommended statement is fully supported by the cited reference. However, FDA agrees with the commenter's broader implication that there are many benefits to interpreting a mammogram in comparison to one or more of the patient's previous mammograms, including but not limited to improved accuracy and reduced recall rate. FDA believes that the final rule adequately reflects the value of making comparisons to previous mammograms when available.

(Comment 44) Some comments express concern about the timing of interpretation of a mammogram following an assessment of ''Incomplete: Need prior mammograms for comparison.'' A comment asserts that a patient may not be able to obtain prior mammograms within 30 days, and another comment asserts that the rule would permit a total of 60 days from the performance of the examination to the final interpretation, assuming 30 days to obtain the prior examination and another 30 days to make the comparison and issue a final report, and that during that time the patient's insurance or healthcare provider may change. One of the commenters recommends that FDA impose a total limit of 30 days from the performance of the examination to the issuance of the final report, and one recommends that FDA monitor the use and benefit of the new assessment category.

(Response 44) A facility is required to issue a report to the referring healthcare provider and a summary in lay terms to the patient no later than 30 days after the examination (§ 900.12(c)(3)(i)), and to issue a followup report no later than 30 days after issuing an initial report of ''Incomplete: Need prior mammograms for comparison,'' whether or not comparison views can be obtained (§ 900.12(c)(1)(v)(B) in this final rule). However, we note that these 30-day intervals are maximums, and represent baseline standards. There is no requirement that a facility wait a full 30 days for a patient to submit prior images, and likewise no requirement that a facility wait a full 30 days after receiving a prior comparison examination before issuing a final report. A facility may establish policies regarding a shorter interval to wait for prior examinations and a shorter interval in which to issue a final report after receiving comparison examinations, perhaps with exceptions for a patient's individual situation. Therefore, FDA concludes that the reporting deadlines stated in the regulations as proposed and finalized are adequate. FDA also notes that although the two ''Incomplete'' assessment statements are new to the quality standards regulations, they are derived from the ''Incomplete'' assessment statement approved in alternative standard #11 in 2003 (Ref. 25) and in widespread use since that time. FDA is not aware of any concerns raised about the benefit of the use of this assessment category or concerns about the timing of the final report. The Agency further notes that the report is required to be sent to the healthcare provider who referred the patient for the mammogram, unless the patient informs the facility of a new or additional provider (§ 900.12(c)(3)).

(Comment 45) A comment expresses opposition to the new assessment statement ''Incomplete: Need prior mammograms for comparison,'' asserting that this will lead to an increase in the number of mammograms that either do not receive a final assessment within 30 days, or do not receive one at all.

(Response 45) FDA disagrees with this comment. First, as noted in Response 44, this assessment statement is derived from one that has already been eligible for use since 2003 under the approved alternative standard #11 (Ref. 25). Furthermore, in this final rule, use of the assessment statement ''Incomplete: Need prior mammograms for comparison'' in § 900.12(c)(v)(B) also requires that ''a followup report with an assessment category identified in paragraphs (c)(1)(iv)(A) through (E) of this section must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained.'' Thus, the imperative to issue a final assessment for the examination within 30 days is directly linked to the initial use of this incomplete assessment category. As noted, since the time that alternative standard #11 was approved in 2003, FDA has not become aware of any concerns raised about the timing or issuance of the final report.

H. Deadlines for Mammography Reports

(Comment 46) A comment recommends that the report to the healthcare provider and the lay summary to the patient should have the same deadline of 14 days. A separate comment recommends that screening mammograms should have a deadline for reports and lay summaries of 30 days from the date of the examination. Another comment recommends that when prior mammograms are needed for comparison, the report should have a deadline of 14 days and the lay summary a deadline of 21 days, respectively, from the receipt of the prior mammogram, not from the date of the current examination.

(Response 46) FDA disagrees with these comments. The deadline of 30 days from the date of the examination (or from the date of the initial Incomplete report, if applicable) is a maximum and a baseline standard. As noted in Response 44, facilities may choose to establish policies of shorter deadlines for releasing prior examinations and for performing comparisons to prior examinations. FDA concludes that the deadline stated in this final rule is adequate. Aside from the specific audit provisions in § 900.12(f), the MQSA and FDA's implementing regulations do not distinguish between mammograms whose clinical role is screening or diagnosis. All examinations must meet the reporting deadlines, and the commenter's recommendation of a 30-day deadline is generally consistent with the regulations. FDA concludes

that the deadline for the report should be linked to the date of the examination. This is because the receipt of prior comparison examinations may be unpredictable and inconsistent, and using the date of receipt of prior examinations as opposed to the date of the current examination for the reporting deadline could lead to delays in reporting.

(Comment 47) Several comments note an inconsistency between, on the one hand, the 30-day deadlines for all mammography reports (§ 900.12(c)(3)(i)) and lay summaries (§ 900.12(c)(2)), and on the other hand, the new earlier deadlines for the report of 14 days (in proposed § 900.12(c)(3)(ii)) and lay summary of 21 days (in proposed § 900.12(c)(2)) when a mammogram is interpreted as ''Suspicious'' or ''Highly Suggestive of Malignancy.''

(Response 47) FDA agrees with the comments and acknowledges that these proposed deadlines were inconsistent with respect to deadlines calculated from the date of the mammographic examination. Accordingly, in this final rule we are revising § 900.12(c)(2) by deleting the words ''but in no case later than 21 calendar days from the date of the mammographic examination,'' and revising § 900.12(c)(3)(ii) by deleting the words ''but in no case later than 14 calendar days from the date of the mammographic examination.'' All reports and lay summaries, regardless of the assessment of the mammogram, must be sent within 30 calendar days of the examination (see § 900.12(c)(2) and (3)(ii) in this final rule). However, as noted in Response 46, this 30-day deadline is a maximum and a baseline standard. In many facilities, the interpretation and communication of the results is typically performed much sooner than at 30 days. Accordingly, we consider the within-30-day timeframe of the mammographic examination to be appropriate, except in the following circumstances: We require that, for positive mammograms (defined as mammograms with an assessment category of either suspicious or highly suggestive of malignancy (see § 900.2(mm)), the facility send both the report and the lay summary within 7 calendar days of the final interpretation of the mammogram. For these situations, the deadline for providing the lay summary is earlier than the general 30-day deadline from the date of the mammographic examination for all reports and lay summaries (see §§ 900.12(c)(2) and (c)(3)(ii) in this final rule). As discussed in the proposed rule (84 FR 11676), FDA believes such action by the facility is appropriate for these two final assessment categories because they both indicate findings that warrant further evaluation.

We have noted an additional inconsistency, regarding the deadlines for sending a report to a ''self-referred'' patient who has not identified a referring healthcare provider. A self-referred patient receives both the lay summary and the mammography report. As discussed above (in this response), the timeframe for sending the lay summary to any patient, including a self-referred patient, is within 30 days of the performance of the examination, and within 7 days of interpretation if the assessment is ''Suspicious'' or ''Highly Suggestive of Malignancy'' (see § 900.12(c)(2) in this final rule). The timeframe for sending the report to the self-referred patient is within 30 days of the examination (see § 900.12(c)(2)(i) in this final rule), but the proposed rule did not specify any change in that deadline when the results are suspicious or highly suggestive of malignancy. We are now adding the statement ''If the assessment of the mammography report is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility shall send this report to the patient within 7 calendar days of the final interpretation of the mammograms'' (see § 900.12(c)(2)(i) in this final rule). This addition makes the 30-day and 7-day deadlines consistent for sending the mammography report to either the referring provider (if a patient identifies a provider) or directly to a patient who has not identified a provider.

I. Breast Density Notification—General Support for Density Notification

(Comment 48) FDA received comments that support the proposed requirements to provide information regarding breast density to both patients and their healthcare providers, with comments recommending that FDA finalize the regulations with the two categories of breast density in patient lay summaries and four categories in reports to healthcare providers as proposed.

(Response 48) FDA appreciates the public support for the density notification requirement. FDA believes that receiving consistent baseline information regarding breast density is important for both patients and their healthcare providers to make informed shared decisions, and that the respective requirements for the report and lay summary strike an appropriate balance between providing sufficient information to healthcare providers while maintaining a clear message to patients. Therefore, in this final rule, FDA is requiring that the breast density notification use two categories of breast density in the lay summary to patients (see § 900.12(c)(2)(iii) and (iv)) and four categories in the report to healthcare providers (see § 900.12(c)(1)(vi)(A) through (D)).

(Comment 49) A comment states that the proposed rule creates a standard that is not backed by medical evidence.

(Response 49) FDA disagrees with this comment. The commenter is referring to the requirement for breast density notification. Both the proposed amendments and this final rule do not specify the further management of patients with dense tissue, only that these patients and their providers must be notified of their breast density. As discussed in Response 62, the Agency is revising the notification to patients with dense breast tissue to reflect that ''In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers.'' (see § 900.12(c)(2)(iv) in this final rule), which is supported by many scientific studies demonstrating increased cancer detection in dense breasts using supplemental imaging modalities (Refs. 10, 11, 31, and 32). This increased detection facilitates earlier treatment of mammographically occult cancers, and may reduce morbidity from the tumor and its treatment.

(Comment 50) Several comments recommend that the lay summary should contain simple, clear language, and several comments recommend that the density information should be placed at the top of the letter instead of following the result or assessment statement.

(Response 50) FDA agrees with the recommendation that the lay summary should contain clear language. In this final rule, both of the revised notification statements for the lay summary are below the eighth grade reading level on the Flesch-Kincaid scale. We conclude that the notification language represents a balance of understandability and accuracy (see § 900.12(c)(2)(iii) and (iv) in this final rule). However, the Agency does not agree that it is necessary to require that the breast density notification statement be placed in a specific location relative to other mammogram result information in the lay summary. We incidentally note that the lay summary is not required to include an assessment category or statement. Furthermore, given the range of mammogram results and recommendations that may need to be communicated by a facility to a patient, we conclude that it may be unduly restrictive to make this a requirement for facilities, and that it

may potentially be confusing to patients.

(Comment 51) A comment recommends that an explanation of medical terms must be included in all lay summaries.

(Response 51) FDA disagrees with the comment. We note that the language for the lay summary in this final rule excludes medical terminology that may not be understandable to a wide audience. We do not believe that it is necessary to require that an additional explanation of medical terms be included in a lay summary.

(Comment 52) A comment recommends that the lay summary include additional information about mammography and its limitations.

(Response 52) FDA disagrees with requiring this information in the lay summary. The language in this final rule for the lay summary includes the statement that ''Dense tissue makes it harder to find breast cancer on a mammogram,'' and FDA concludes that this statement is adequate in addressing the limitations of mammography as they relate to breast density. As is also stated in the breast density notification language (see § 900.12(c)(2)(iii) and (iv) in this final rule), FDA recommends that patients speak to their healthcare provider after receiving the lay summary, and this discussion can include more information on mammography and its limitations.

(Comment 53) A comment recommends that FDA work with individuals to improve the readability and understandability of any proposed language and describes existing breast density notification language as poor in understandability and causing confusion and misinformation.

(Response 53) The breast density notification language in this final rule is the result of discussion between clinicians, patients, and FDA. Both the notification statement to patients with non-dense breasts (see § 900.12(c)(2)(iii) in this final rule) and the notification statement to patients with dense breasts (see § 900.12(c)(2)(iv) in this final rule) are below the eighth grade reading level on the Flesch-Kincaid scale. We believe that these statements represent an appropriate balance between patient understandability and accuracy of the information conveyed. FDA cannot comment on the understandability of various State breast density notifications; however, FDA recommends that patients speak to their healthcare provider about any language that they do not understand.

(Comment 54) A comment recommends that visual aids and medical cartoons for patients with low literacy should be included, to decrease health disparities.

(Response 54) FDA acknowledges that patients of limited literacy may need assistance with the interpretation of the lay summary. However, FDA does not believe it is necessary to require this information in the summary. The requirements for the lay summary represent baseline standards; FDA recognizes that facilities may choose to provide additional information or explanation they feel is needed by their patients. The breast density notification language in this final rule is meant to be concise and clear, and adding visual aids and medical cartoons into the lay summary may potentially distract from the primary message regarding a patient's breast density and resulting recommendations. FDA notes that the interaction between a patient and their healthcare provider presents an appropriate opportunity to address questions that a patient may have regarding the lay summary. The required language in this final rule (§ 900.12(c)(2)(iii) and (iv)) includes such a recommendation to talk to a healthcare provider.

(Comment 55) Several comments recommend that in addition to the breast density notification, FDA add patient education and a clear plan of management to the lay summary.

(Response 55) FDA disagrees with the comment. We conclude that the language in this final rule provides a foundation for patients to be informed regarding their breast density when using mammography. The intent of the lay summary being required and provided to the patient is not to serve as an exhaustive resource regarding breast disease and its management. The lay summary includes the recommendation for the patient to talk to their healthcare provider, and we note that this interaction is an appropriate opportunity for additional patient education. Regarding the recommendation that the lay summary include a clear plan of management, FDA notes that the lay summary is generated by the breast imaging facility, whereas the plan of clinical management for each individual patient will be developed by the patient and their healthcare provider, and as such, it is not appropriate for this type of information to be included in the lay summary.

(Comment 56) A comment recommends replacing the phrase, ''The breasts are almost entirely fatty,'' in § 900.12(c)(1)(vi)(A), with the phrase, ''The breast tissue is of low density,'' asserting that the former statement has ''negative connotations'' to many patients.

(Response 56) FDA disagrees with the comment. FDA notes that this category, and the others in § 900.12(c)(1)(vi)(A) through (D), are already in widespread use in breast density reporting. Thus, FDA believes it would be confusing to replace the ''almost entirely fatty'' category with the ''low density'' sentence recommended by the commenter, as it would be unclear whether ''low density'' referred to the breast density category in § 900.12(c)(1)(vi)(A), ''The breasts are almost entirely fatty,'' or the density category in § 900.12(c)(1)(vi)(B), ''There are scattered areas of fibroglandular density.'' Additionally, the breast density assessment statement in § 900.12(c)(1)(vi)(A) is included only in the report intended for the healthcare provider, and not in the lay summary sent to the patient, so it will not be sent to patients with a referring provider. Self-referred patients will receive the lay summary as well as the report, which should help mitigate any unintended negative connotations of the report.

(Comment 57) A comment questions the benefit of the density notification and recommends that FDA should involve more individuals in the drafting of density notification language, and that this language should describe the limitations of density assessment, the risks of overdiagnosis and overtreatment such as gadolinium exposure from MRI and radiation exposure from additional mammographic evaluation, and the lack of benefit of density notification. A comment recommends adding additional language educating patients about breast density, what it means to a patient, and how patients can take extra steps to protect themselves.

(Response 57) FDA disagrees with the assertion of lack of benefit in informing patients and their healthcare providers of a patient's breast density. FDA considers it to be a benefit to inform patients about their breast anatomy. In addition, FDA considers it to be a benefit to inform patients in a consistent manner about their breast density. The language in the final rule is intended as a baseline for breast density information, which can be used by patients and their healthcare providers to help inform and guide patient care. FDA notes that the provider-patient interaction is an appropriate opportunity for further discussion of breast density and of the benefits and risks of possible further evaluation. We conclude that including too wide a range of information in the lay summary, particularly information that

may not be supported by a wide consensus in the scientific community or current information that may be subject to change with future advances in knowledge and understanding, may unnecessarily increase patient confusion and lead to reduced effectiveness of the breast density notification.

(Comment 58) A comment recommends eliminating the recommendation in § 900.12(c)(2)(iii) for patients with non-dense breast tissue to talk to their healthcare provider. Another comment recommends that patients should be directed to additional information on breast density, not just to their referring physician.

(Response 58) The Agency believes it is important for patients to have an understanding of their breast density to promote informed and shared decision making about whether supplemental screening is appropriate based on each patient's individual circumstances, and speaking with their healthcare provider is an additional opportunity to accomplish this. The final rule does not prohibit facilities or healthcare providers from providing additional information on breast density to patients; however, FDA concludes that specific additional resources on breast density should not be codified in the final rule as a requirement to be provided as part of the lay summary, particularly since these sources of information may change or become outdated.

(Comment 59) A comment asserts that there are conflicting reports of the density discussion at the 2011 NMQAAC meeting.

(Response 59) FDA disagrees with the comment. A transcript of the 2011 NMQAAC meeting is available (Ref. 33). The transcript shows there was general agreement on requiring density notification and advising patients to speak with their healthcare providers. In 2011, there was some disagreement among the members of the Committee on particular issues such as the definition of a dense breast, the degree of cancer risk conferred by dense breast tissue, and recommendations for further evaluation of patients with dense breasts. FDA notes that since 2011 there is now greater consensus in the scientific and medical practice community on the categorization of breast density and the degree of risk it confers, and also greater availability of imaging modalities for supplemental screening (Ref. 31). This final rule only recommends that patients speak with their providers, and does not make any specific recommendations for further imaging or other evaluation, which is more appropriately reserved for the unique clinical decision-making process that takes place between a patient and their provider.

(Comment 60) A comment recommends that there be four different patient notification statements in the lay summary rather than two. A comment recommends adding detailed explanatory information regarding breasts as ''dense'' or ''not dense,'' or adding a four-category patient density notification.

(Response 60) FDA concludes that the two patient notification statements (*i.e.,* informing patients that they have ''dense'' breast tissue or ''not dense'' breast tissue) provide a clear message to patients regarding their breast density, and that generating four different categories, each with unique language in the lay summary, would potentially add confusion for some patients, as well as an increased burden on facilities. FDA concludes that the language in this final rule for the lay summaries (§ 900.12(c)(2)(iii) and (iv)) provides an adequate baseline for breast density notification to patients given that the purpose of the letter is not to serve as a complete resource for breast density information and, further, that the inclusion of more detailed information might detract from the actual notification, including by dissuading patients from reading the notice at all, given its length.

(Comment 61) A comment asserts that there is variability and limited reproducibility in the determination of dense versus non-dense breasts, and that if this variation is expressed as changing assessments, women may lose confidence in the screening mammography process.

(Response 61) FDA acknowledges that for some patients there may be some degree of variability in the determination of breast density due to interobserver and intra-observer variability. FDA notes that there have been advancements in technology (*e.g.,* density classification software devices) that may help mitigate such variability in assessment. In addition, we conclude that potential variability in density assessment does not outweigh the importance of communicating breast density to patients and their healthcare providers. FDA disagrees with the comment that patients will lose confidence in mammography if their breast density assessment changes. If a patient has any concerns regarding any aspect of the mammogram, including the breast density assessment, the patient may contact the referring provider or the mammography facility. This final rule contains requirements for facilities regarding providing mammogram studies and reports to patients upon request (§ 900.12(c)(4)).

(Comment 62) A comment recommends that the final rule not contain the statement that some patients with high breast density may need other imaging tests in addition to mammography, as this is not supported by evidence, and may lead to false positives, overtreatment, and overdiagnosis.

(Response 62) The language in the final rule is not intended to require additional imaging evaluation for patients with dense breasts, but rather to provide a baseline of information for discussion between a patient and their healthcare provider. Accordingly, we are revising this sentence of the notification to reflect that other imaging tests in addition to a mammogram may help find cancers, as opposed to stating that some patients with dense tissue ''may need'' additional imaging. The notification in this final rule states, in part, that ''In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers.'' (see § 900.12(c)(2)(iv) in this final rule). The density notification requirement does not specify additional clinical management, but the Agency believes that the communication of breast density information is important for a patient to better understand their own situation and to facilitate joint decision-making by the patient and the healthcare provider.

(Comment 63) A comment recommends that FDA withdraw the requirement for breast density notification to patients from the final rule until better evidence is available, asserting that breast density notification will cause undue worry for women without specific actions they can take.

(Response 63) FDA disagrees with the recommendation to withdraw the requirement for breast density notification to patients. We conclude that there is already adequate support for informing patients of their breast density, and while we do not believe that it is appropriate for this final rule to contain requirements regarding specific followup imaging tests, this rule does contain the recommendation for a patient to discuss their breast density and individual situation with their healthcare provider.

(Comment 64) A comment recommends that FDA allow variation in the wording of the breast density notification in the lay summary and states that the commenter's State already requires density reporting with the use of four density categories.

Another comment states that FDA already has density wording.

(Response 64) FDA disagrees with the recommendation to allow variations in the wording of the density notification. The required breast density notification language in this final rule is intended to provide a uniform density notification; however, the final rule does not prohibit facilities from providing patients with additional information regarding breast density. FDA disagrees with the assertion that there was already density notification wording provided by FDA prior to the publication of this rule.

(Comment 65) A comment recommends that increased risk of breast cancer be included in the lay summary for patients with dense breasts, and that qualifying words such as ''may'' be eliminated.

(Response 65) FDA agrees with the recommendation to include a statement in the lay summary about the increased risk of breast cancer associated with dense tissue (see Response 75). We are revising the notification language in this final rule, including the sentence ''Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer'' (see § 900.12(c)(2)(iii) and (iv) in this final rule). The word ''may'' is used in the revised statement that ''In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers'' (see § 900.12(c)(2)(iv) in this final rule). FDA believes that this language in the lay summary is appropriate for communicating breast density information and recommendations without causing undue alarm to patients.

(Comment 66) A comment recommends adding BI–RADS density categories to the MQSA regulations.

(Response 66) We note that the breast density assessment statements in the report to the healthcare provider, as written in § 900.12(c)(1)(vi)(A) through (D) in this final rule, correspond to the wording of the density categories in the BI–RADS 5th edition (Ref. 34) (see also Response 35).

(Comment 67) A comment recommends that facilities be required to have different lay summaries, for those given to patients at ''time of service'' and for those that are mailed.

(Response 67) FDA does not agree that it is necessary to require facilities to have different versions of the lay summary based on when the letter is delivered to the patient. This final rule does not prohibit a facility from adopting such a practice, but the required language in § 900.12(c)(2) must be included in any version of the lay summary.

(Comment 68) A comment specifically recommends that the lay summary make it clear to a patient whether their breast density is high or low.

(Response 68) As addressed in Responses 76 and 79, we are revising this final rule and replacing the wording of high density and low density with ''dense'' and ''not dense,'' respectively (see § 900.12(c)(2)(iii) and (iv) in this final rule). We conclude that these revised terms will be clearer to patients. FDA believes that the language in the final rule for the lay summaries is adequate and accomplishes its intent of communicating breast density information and recommendations to patients.

(Comment 69) A comment recommends that before finalizing the rule, FDA should document the benefits of breast density notification and ensure that unintended harms are avoided.

(Response 69) FDA notes that communicating breast density to patients is an important component of empowering them to make decisions regarding their healthcare, and is the primary benefit of the breast density notifications set forth in this rulemaking. As most States already have breast density notification requirements, which vary across the country (Ref. 8), FDA concludes that it is important to have a consistent baseline for the content of these notifications. Some patients with dense breast tissue and other risk factors may be advised by their providers (based on their individual risk factors) to undergo supplemental screening, such as with ultrasound, which has been shown to increase cancer detection, particularly of small and node-negative cancers (Ref. 32); this early detection may decrease morbidity from the cancers and their treatment.

(Comment 70) A comment recommends that FDA should support development of an evidence base and guidelines for care for women with dense breasts, which can then be used to develop and provide educational materials to clinical providers in providing evidence-based supplemental screening recommendations.

(Response 70) FDA disagrees with the comment. There are many existing resources, including recommendations from professional societies and a large base of literature, that already provide recommendations on care for patients with dense breasts (including, but not limited to Refs. 10, 12 to 14, 28, 31, and 33 to 37). The MQSA implementing regulations (including this final rule) are designed to ensure that patients in the United States have access to quality mammography services.

(Comment 71) Some comments recommend that breast density notification should not be required in the lay summary sent to women in the non-dense categories, and that if FDA requires breast density notification to women in these categories, that verbiage describing the implications of having dense tissue be minimized.

(Response 71) FDA disagrees with the comment. The Agency believes that it is important to communicate information regarding breast density to patients in all density categories. FDA concludes that the language in this final rule for the lay summary for patients who have non-dense breasts (see § 900.12(c)(2)(iii)) is of an appropriate level of detail and provides context for the breast density notification.

(Comment 72) A comment asserts that the way that risk is described by statisticians and epidemiologists, for example by comparing the risk of breast cancer between women whose breast tissue is at the extremes of greatest and least density, is misleading to the average lay person.

(Response 72) FDA notes that the language in this final rule for breast density notification in the lay summary does not communicate risk information to patients in the manner in which the commenter asserts risk information is described by statisticians or epidemiologists. As addressed in Responses 68, 75, 76, and 79, we have revised the notification statements to patients with both dense and non-dense tissue to say, in part, ''Dense tissue . . . raises the risk of developing breast cancer'' (see § 900.12(c)(2)(iii) and (iv) in this final rule).

(Comment 73) Several comments recommend that information on next steps needs to be included with the dense tissue notification to patients. Another comment recommends that more specific recommendations be given beyond discussing breast density with a healthcare provider, that radiologists should be specific in recommending additional imaging studies, and that all possible imaging modalities that may be more effective than mammography should specifically be mentioned in the lay summary.

(Response 73) The language in this final rule for the patient lay summary for patients with dense breasts (see § 900.12(c)(2)(iv)) includes the recommendation to speak with the patient's healthcare provider regarding breast density, breast cancer risk, and the patient's individual situation. FDA concludes that it is not appropriate to indicate any additional steps in a

patient's care prior to this interaction and based only on the mammogram, as individual situations and risk factors vary. FDA does not agree that it is appropriate to require the lay summary to include a discussion of all possible breast imaging modalities that may be more effective for some patients than mammography, as this would require a significant amount of information that may be difficult for patients to interpret. We believe that it is more appropriate for the healthcare provider to discuss this information with the patient and engage in shared clinical decision-making based on the patient's individual circumstances. This rule does not prohibit a facility from providing further information to patients in addition to the required language in the final rule if the facility chooses to do so.

J. Breast Density Notification Language

(Comment 74) Several comments recommend deleting the phrase ''more glands than fat in the breasts'' from § 900.12(c)(2)(iii), asserting that it is inaccurate because: (1) the ratio of fat to glandular tissue is not always related to density on mammography due to regional variation of fat and glandular tissue as well as a fibrous tissue component; (2) fibrous tissue is distinct from glandular tissue and often accounts for the majority of the density seen on mammograms; and (3) dense breasts have more fat than dense tissue when quantified. Another comment asserts that the breast density depends upon other factors, such as the glandular tissue and stroma projecting together, the compliance of the breast under pressure of the compression paddle and the amount of fat in the macroscopic component of stroma.

(Response 74) FDA acknowledges the presence of fibrous stroma in the composition of the breast, and agrees with the comments regarding the many anatomic, technical, and other factors that contribute to mammographic breast density. We also agree with the recommended deletion. Accordingly, we have deleted the phrase ''more glands than fat in the breasts'' from the density notifications in § 900.12(c)(2)(iii) and (iv) of this final rule. Additionally, this final rule does not use the term ''glandular tissue'' in either the assessment of breast tissue density in the report to the healthcare provider (see § 900.12(c)(1)(vi)(A) through (D)) or the notification of density in the lay summary to the patient (see § 900.12(c)(2)(iii) and (iv)).

(Comment 75) Several comments recommend modifying the language in the patient lay summary in proposed § 900.12(c)(2)(iv) to include a statement that higher breast density raises a patient's risk of developing breast cancer.

(Response 75) FDA agrees with the comments, and notes that studies show that women with dense breast tissue do have an elevated risk of developing breast cancer (Refs. 12 to 15). Accordingly, we have added to the patient notification language in § 900.12(c)(2)(iii) and (iv) of this final rule, a statement that ''Dense tissue . . . raises the risk of developing breast cancer.''

(Comment 76) Several comments recommend that FDA adopt the density notification language proposed by two commenters. This language includes: (1) a revision of FDA's proposed introductory sentences beginning with ''Some patients,'' out of concern that they will cause alarm to patients with non-dense breasts and confusion to patients with dense breasts; (2) a recommendation to include an elective option to use four density categories in States whose notification regulations require this; (3) a recommendation to substitute the term ''scattered fibroglandular tissue'' for the term ''scattered areas of fibroglandular density'' in the mammography report, to avoid patient confusion of the phrase ''scattered . . . density'' with tissue that is ''dense''; (4) a recommendation that patients with non-dense breasts should not be advised to speak to their provider; (5) a recommendation that patients be advised to continue routine screening mammography; and (6) a recommendation to add a statement that risk factors such as density can change.

(Response 76) FDA appreciates these comments. As described in the following and organized according to the numbered topics identified in Comment 76, we are revising some of the wording in the final rule for the lay summary.

(1) We have modified the introductory language to remove the reference to ''Some patients,'' but we disagree with the assertion that providing some basic information about density will cause alarm to patients with non-dense breast tissue or confusion to patients with dense breast tissue.

(2) As addressed in Responses 68 and 79, we have retained the two categories of density, but changed the wording from the comparative terms ''high density'' and ''low density'' to ''dense'' and ''not dense,'' in order to provide a clear message to the patient. We have also corrected § 900.12(c)(2) to specify that the lay summary shall include ''an assessment of breast density as described in paragraphs (c)(2)(iii) and (iv) of this section'' (*i.e.,* the two categories of ''dense'' and ''not dense''). In States where notification using four density categories is required by State law, facilities may also provide that information to patients, but this is distinct from the notification paragraph required by this MQSA final rule.

(3) As the commenter notes, the phrase ''scattered areas of fibroglandular density'' is only required in the report intended for the healthcare provider, where this phrase conforms to current clinical practice and should not cause confusion to healthcare providers. One of the goals of the MQSA and its implementing regulations is ensuring clear communication between the IP and the referring provider; therefore, the report is written using medical terminology. The phrase is not required in the lay summary to the patient; therefore, we do not agree that the phrase will cause patient confusion. For all patients, whether referred by a provider or self-referred, the lay summary will only contain a clear statement that the patient's breast tissue is ''dense'' or ''not dense.'' Patients who are self-referred will also receive the report, but the lay summary should help avoid confusion. Even a patient who is self-referred for a mammogram may give the report to their healthcare provider; therefore, the precision of the report should not be sacrificed in order to tailor the language to the lay patient, who will also receive a lay summary.

(4) Regarding the commenter's recommendation that FDA should remove the advice for patients whose tissue is assessed as ''not dense'' to discuss breast density with a healthcare provider, FDA disagrees with this recommendation, as we believe that this conversation is appropriate for patients in all density categories.

(5) In response to the recommendation to add a statement instructing patients to continue routine screening mammograms, we believe that is part of a larger discussion, including regarding screening methods and time intervals, that should take place between a patient and the patient's healthcare provider.

(6) In response to the recommendation to add a statement that breast density and other risk factors can change, FDA concludes that adding this statement in the lay summary may be confusing and may detract from the information provided regarding the current assessment of the patient's breast density.

(Comment 77) Several comments recommend that not all women should be informed of breast density risks, and that notifying all women is ineffective

and doing so may cause confusion. Another comment recommends that breast density language should only be included in lay summaries to women with dense breast tissue.

(Response 77) FDA disagrees with the comments. A primary goal of this provision of the final rule is to provide information to patients and their healthcare providers to help guide each individual patient's care. Therefore, as noted in Response 76, FDA believes that it is appropriate for patients in all density categories to discuss breast density with their healthcare providers. The intent of this final rule is to provide breast density information to all patients and their healthcare providers to help guide each patient's care.

(Comment 78) A comment recommends that patients should be encouraged to discuss their mammography findings with their physician to determine what additional tests may be beneficial in their specific circumstances.

(Response 78) FDA agrees with the comment, and concludes that the current wording in the final rule, § 900.12(c)(2)(iii) and (iv), accomplishes this.

(Comment 79) Several comments recommend using the terms ''dense'' and ''not dense'' rather than ''high density'' and ''low density.''

(Response 79) FDA agrees with this recommendation to improve clarity and reflect clinical practice. Accordingly, as noted in Responses 68 and 76, we are revising the final rule to now state, in § 900.12(c)(2)(iii), ''Your breast tissue is not dense,'' and in § 900.12(c)(2)(iv), ''Your breast tissue is dense.''

(Comment 80) A comment recommends clarification on whether FDA will provide acceptable alternative breast density reporting language, and requests that FDA consider replacing the breast density notification language with a list of required key information points proposed by one commenter.

(Response 80) FDA disagrees with the comment. One of the intents of this rulemaking is to ensure that patients receive a consistent baseline of information regarding their breast density; additionally, the notification should be subject to straightforward verification during the MQSA inspection. Therefore, the Agency is not providing alternative breast density reporting language aside from that which is included in the final rule, nor changing the notification requirement from a required paragraph to a list of key points. FDA recognizes that individual States as well as facilities may choose to provide patients with additional information, beyond the information required in this final rule, where it does not conflict with the MQSA and its implementing regulations.

(Comment 81) A comment recommends that FDA be cautious in the use of the word ''normal'' when referring to women with dense breasts, since dense breasts may be pathologic and should be a subject of research for disease prevention. Conversely, several comments recommend that lay summaries should state that dense breasts are not abnormal.

(Response 81) FDA agrees that it is not necessary to characterize dense breast tissue as normal or abnormal, but rather to focus on communicating whether a patient has breast tissue that is dense or not dense. In this final rule, FDA does not use the words ''normal'' or ''abnormal'' in the breast density notification statements for patients with either dense or non-dense breast tissue.

(Comment 82) A comment recommends that the lay summary should emphasize that dense breasts are common and that most women with dense breasts do not reach the clinical threshold for having an elevated risk for breast cancer.

(Response 82) FDA agrees that dense breast tissue is common; however, we disagree with the comment regarding elevated risk of cancer. We note that studies show that women with dense breast tissue do have an elevated risk of developing breast cancer (Refs. 12 to 15), and as noted in Response 75, we are revising the patient notification language (see § 900.12(c)(2)(iii) and (iv) in this final rule) to include a statement that dense tissue raises the risk of developing breast cancer.

(Comment 83) A comment recommends that FDA include recommendations to use FDA-cleared automated breast density assessment devices, and that instead of the four categories of breast density proposed for the report to the healthcare provider, breast density should be reported along a continuum based on such automated breast density devices.

(Response 83) FDA acknowledges that there are various methods for the assessment of breast density, which may include automated processes such as FDA-cleared density assessment software devices. However, the categories in § 900.12(c)(1)(vi)(A) and (D) of this final rule are consistent with the four ACR BI–RADS categories of breast composition, which are ''defined by the visually estimated content of fibroglandular-density tissue within the breasts'' (Ref. 34) and do not require automated assessment. The MQSA and implementing regulations do not require the purchase or use of specific products as a condition of facility certification, and ABs may not require the purchase or use of specific equipment or software as a condition of facility accreditation (see § 900.4(a)(5)). Furthermore, not all facilities may have or be able to afford the same equipment or software, and requiring specific equipment could potentially limit access to mammography services. Finally, the four density categories in this final rule are in wide use in current clinical practice, and will be more readily understood by clinicians than a report of individual results along a continuum.

(Comment 84) A comment recommends that the lay summary specify how dense breast tissue impacts the statistical accuracy of mammography.

(Response 84) FDA disagrees with making this a requirement of the lay summary. The Agency notes that any information included in the lay summary must account for patient understandability. FDA concludes that including a discussion of statistics in the lay summary may detract from the effectiveness of the breast density notification and recommendations. Additionally, knowledge of breast conditions and disease processes is subject to change with ongoing research, and specific statistical information may become outdated and misleading. However, as noted in Response 52, we are revising the notifications to include the statement that ''Dense tissue makes it harder to find breast cancer on a mammogram. . . .'' (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that this language adequately conveys the existence of a masking effect of dense tissue on mammography.

(Comment 85) Several comments recommend that the lay summary use four categories for breast density, similar to the report to the healthcare provider; however, the language used in the lay summary should be written at an appropriate education level. Another comment recommends adding the word ''significantly'' in reports for patients with extremely dense breasts.

(Response 85) FDA does not consider it necessary to use four categories of breast density in a lay summary. In clinical practice, further management decisions are typically based on the distinction between non-dense and dense, *i.e.,* two categories, as well as on other patient risk factors. The Agency believes that the two categories for breast density in the lay summary represent an appropriate balance between patient understanding and precision of the underlying information.

We believe that using four categories rather than two in the lay summary would not be more effective in communicating breast density information, and that doing so may be confusing to patients and burdensome to facilities. As noted in Response 60, we are revising § 900.12(c)(2) to specify that the lay summary shall include ''an assessment of breast density as described in paragraphs (c)(2)(iii) and (iv) of this section,'' *i.e.,* the two categories of ''dense'' and ''not dense,'' and have simplified the language used in these patient notifications.

Similarly, we note that adding the word ''significantly'' would effectively divide the single category of dense breast tissue into two categories, and detract from the goal of providing a clear message to patients with dense breast tissue. Also, this may cause undue alarm to patients, as this term is subjective and will not be consistently interpreted by all patients. The healthcare provider will receive the report that assesses the density on a four-category scale, and can incorporate this information into their clinical recommendations to the patient.

(Comment 86) A comment recommends that when a patient views their online medical chart from their primary care physician, rather than a report that describes their breast density, the patient's actual mammogram images should be displayed, and the patient can assess where their own density is located along a normal distribution.

(Response 86) FDA agrees that patients should be informed and empowered in the decision-making related to their healthcare. Therefore, this final rule includes the requirement for mammography facilities to directly notify patients of their breast density in the lay summary (see § 900.12(c)(2)(iii) and (iv)), not through viewing a primary care provider's medical chart. However, we disagree with including an image display requirement for several reasons. First, the primary care physician or other referring healthcare provider may not have the mammogram images, unless the patient has requested that the images be sent to that provider (see § 900.12(c)(4)(ii) and (iii)). Also, requiring primary care physicians to display online medical charts in a specific manner is not within the scope of the MQSA; furthermore, not all patients may choose to access online charts even when these are made available. We also conclude that it is not reasonable to expect patients to assess their own breast density and generate plans for followup based on their self-assessment. Finally, we note that providing patients with the images from their mammogram studies when requested continues to be a requirement in the final rule (see § 900.12(c)(4)(ii) and (iii)), so if patients choose to do so, they can directly obtain their mammogram images from the performing facility, without any need to use their primary care provider as an intermediary.

(Comment 87) A comment recommends that, due to the variety of recommendations for patients with dense breasts, the lay summary should include a statement to follow the recommendations in the lay summary and in the report sent to the patient's healthcare provider.

(Response 87) The Agency finds that the notification language in this final rule for patients assessed to have dense breast tissue (see § 900.12(c)(2)(iv)) is adequate. In the course of the clinical decision-making, the referring provider will typically read and interpret the mammography report, including its recommendations, in the context of other clinical information about the patient. We also note that all patients will receive the lay summary, but most patients (except for those who are self-referred) will not receive the report that is sent to the referring healthcare provider. A referred patient would therefore not typically have the ability to independently follow the recommendations in that report. Although the lay summary does not explicitly state that patients should follow the recommendations in the report to the patient's healthcare provider, it does state that patients should speak with their healthcare provider. That interaction is an opportunity for the patient to receive recommendations from their healthcare provider.

(Comment 88) A comment recommends that the lay summary should encourage patients and referring providers to discuss mammogram results with the radiologist who interpreted the mammogram. Another comment recommends that patients should have the opportunity to speak with the radiologist.

(Response 88) FDA interprets the word ''radiologist'' to mean the IP, as the majority of qualified IPs under the MQSA and its implementing regulations are radiologists. We agree that the IP for a mammogram is a potential resource for both patients and their healthcare providers, and this final rule does not prohibit communication between these parties. However, we conclude that it is neither necessary nor practical to include a recommendation for patients and healthcare providers to discuss the results of every mammogram with the IP. Workflow varies across facilities; many mammograms are interpreted in batches at times when the imaged patients are not present, and many mammograms are interpreted at sites other than the facilities where the images were performed. Therefore, the IP may not be readily available to speak to all patients. The recommendations to encourage all patients to discuss their results with the IP, or to require the facility to provide an opportunity for the patient to speak with the IP, are likely to cause a significant burden on IPs and facilities, and could reduce access to mammography services. Furthermore, the referring healthcare provider is likely to have a more complete knowledge of each patient's history and risk factors than the IP, and it is therefore more appropriate for the patient to discuss their results with their provider. There is also no need for the lay summary to encourage the referring healthcare provider to discuss the results with the IP, as the provider does not receive the lay summary (but does receive the more detailed mammography report). Healthcare providers who require additional information after reading a mammography report can typically contact the IP.

(Comment 89) A comment asserts that DBT is considered supplemental to conventional mammography, and recommends that this be made clear in the notification wording, to prevent a large increase in orders for screening breast ultrasound examinations.

(Response 89) FDA disagrees with this comment. The choice of imaging modalities and the various clinical guidelines for breast cancer screening are more appropriately left to the judgment of the referring provider and the IP as part of the clinical decision-making process. However, FDA notes that many facilities that have DBT equipment use this DBT modality for primary screening of many or all of their patients, and do not reserve it only for supplemental screening. Furthermore, as noted in Response 108, with the exception of the medical outcomes audit (see § 900.12(f)(1) in this final rule), the MQSA and its implementing regulations do not distinguish between screening and diagnostic mammograms. Under the MQSA and its implementing regulations, DBT is a mammographic modality, and is subject to MQSA quality standards and requirements, including the reporting requirements. Therefore, under this final rule, the lay summary for a DBT examination, just like the lay summary for a screen-film mammogram or a full-field digital

mammogram, must include the breast density notification that is appropriate to the patient's breast tissue (see § 900.12(c)(2)(iii) and (iv)). See also Response 2.

(Comment 90) A comment recommends that, in addition to notifying patients about their breast density, the lay summary should also inform patients that ultrasound or MRI may be performed for additional screening. Another comment recommends that the lay summary should explicitly state that for women with dense breasts, it may be appropriate to consider additional imaging tests. Conversely, a comment notes that the U.S. Preventive Services Task Force (USPSTF) has not taken a definitive position regarding supplemental MRI or ultrasound.

(Response 90) In § 900.12(c)(2)(iv) of this final rule, the notification language for patients with dense breasts is being revised to include the statement that ''In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers.'' FDA believes that this information, in addition to the recommendation to discuss breast density with a patient's healthcare provider that is also included in § 900.12(c)(2)(iv), provides a reasonable basis for the patient and the healthcare provider to determine an individual plan that takes into account that patient's breast density. FDA acknowledges that in current clinical practice, ultrasound and MRI examinations are frequently used as imaging modalities in breast evaluation; however, practice can change over time, and therefore we do not believe that it is necessary to specify these particular modalities in the lay summary, but rather, the various options may be discussed by the patient and the healthcare provider. In response to the comment recommending an explicit statement that it may be appropriate to consider additional imaging tests for women with dense breasts, FDA believes that the language in this final rule adequately communicates that other imaging tests may provide benefit in the evaluation of some patients with dense breast tissue. Finally, FDA agrees with the comment about the USPSTF. As noted above in Responses 2, 55, 62, and elsewhere, we have also not specified the further management of patients with dense breast tissue.

(Comment 91) Several comments address the grade level, literacy level, and readability of the notification wording, in general or for particular patient populations. A comment expresses concern that the wording is above the fifth grade level and may cause misunderstanding, confusion, and fear. Another comment recommends that the breast density notification should adhere to FDA's best practices requirement to use plain language and should ensure that the readability is at or below the eighth grade level, or that FDA should explain why this notification is not subject to its general policy on risk communications, and continues that if the reading level exceeds the eighth grade level, FDA should issue a supplemental rule with modified breast density notification. Another comment asserts that the reading level recommended for U.S. women is the fifth to sixth grade level, and recommends that any prescribed language should undergo assessment with tools such as Flesch-Kincaid, Dale-Chall, or the Patient Education Materials Assessment. A similar comment recommends that the Agency should apply textual analysis tools to its proposed notification and consider how to address issues raised with understandability and readability. A comment recommends that if FDA conducted message testing, the results should be made available, and if it did not, it should undertake testing to determine whether the notification is capable of achieving its intended purpose. Another similar comment recommends that FDA should use accepted readability tools to analyze its notification language for readability and understandability, and test the notification among a diverse and representative set of mammography-eligible women, to ensure that it is clear and understandable to all women, and adequately explains all ''hard'' terms, particularly ''breast density.'' Another comment recommends that the Agency should test the notification with an adequate sample of African-American and Hispanic women.

(Response 91) FDA acknowledges these comments. The notification language in this final rule is not intended to be a complete discussion of breast density, but rather to encourage further discussion between each individual patient and their healthcare provider. Readability testing was performed internally by FDA on an earlier draft of the breast density notifications, and although FDA modified the text of the breast density notification from the draft the committee reviewed, FDA incorporated the feedback it received to modify the required breast density notification statements to a lower grade reading level. Many factors, including but not limited to scientific accuracy, adequacy, and readability, were considered in composing the final patient density notifications in this rule. As noted in several responses, in this final rule we are revising both the non-dense and dense breast notifications. The non-dense breast notification (see § 900.12(c)(2)(iii) in this final rule) now states, ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.'' The dense breast notification (see § 900.12(c)(2)(iv) in this final rule) now states, ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.'' Both of these notification statements are below the eighth grade reading level on the Flesch-Kincaid readability scale, which is the average reading level among adults. FDA believes that these notifications and their reading level appropriately balance readability with scientific accuracy and adequacy of information. The Agency also notes that the wording of the notification statements in this final rule is simpler than most of the State breast density notification statements currently used across the country, which are written at a higher reading level (see Ref. 8 for the State notification statements). The simpler language of the Federal notification statements represents a baseline national standard for density notification. FDA notes that further information about appropriate reading levels is also addressed in the response to Comment 92.

(Comment 92) Several comments discuss the research literature on public health messaging in general and breast density notification in particular. A comment recommends that FDA consider the literature on how public health messages are received. Another comment recommends that FDA acknowledge the findings of the Boston University study and other research on the readability and understandability of public health messaging. A comment encourages the Agency to consult the researchers funded by the ACS who are studying the communication of breast density information to women. Another

comment recommends that FDA should assess the State breast density notification requirements to evaluate their benefits to public health, including reviewing the existing literature, and performing an assessment either alone or in partnership with other entities.

(Response 92) FDA acknowledges these comments. We have reviewed some of the research on the readability and understandability of breast density notification, such as References 37 to 40, including the research of the Boston University group (including Refs. 42 to 44). As noted in Responses 52 and 91, FDA believes that the revised notification language in this final rule appropriately balances readability, accuracy, and adequacy, and is simpler than most of the State breast density notifications currently in effect across the country. The revised notification statements in this final rule (see § 900.12(c)(2)(iii) and (iv)) are consistent with the recommendations of most of these researchers, including that the density notification should be written at a lower grade level than most current State density notifications. The Agency agrees with the Boston University researchers (see Ref. 43) that the notification in this final rule should not be the only information a patient receives about breast density, but rather is intended to establish a consistent national baseline standard and to encourage further discussion between each individual patient and their healthcare provider.

(Comment 93) Several comments address the use of languages other than English. A comment recommends that FDA identify and require best practices for disseminating messages about breast density in multiple languages, to reduce anxiety and confusion. Another comment recommends that facilities should be urged or even required to translate the density information into the prevalent or dominant languages of their patient populations. Another comment asserts that there must be a Spanish translation, and recommends that translation into Mandarin, Hindi, or other commonly used languages should also be performed.

(Response 93) FDA acknowledges that patients of limited English literacy may need assistance with the interpretation of the lay summary. However, FDA does not believe that it is necessary to add additional language requirements for the lay summary. The MQSA and its implementing regulations establish baseline national standards. Under the current regulations, the required statements in the mammography report, such as the final assessment statement, are in English. Likewise, the required statements on breast density that this final rule adds to the mammography report (§ 900.12(c)(1)(vi)) and the corresponding required breast density notification statements that this final rule adds to the lay summary (§ 900.12(c)(2)(iii) and (iv)) are in English. Facilities are encouraged to make every effort to communicate with their patients, and FDA recognizes that facilities may choose to provide patients with a translation of the breast density notification statement, but FDA does not believe it is practical for the Agency to regulate such translation. The English-language notification statement in this rule must be included in the lay summary regardless of any additional information or translation that a facility may elect to provide to the patient.

K. Breast Density Notification and the Role of the Referring Healthcare Provider

(Comment 94) Several comments recommend that, in addition to breast density notification, FDA should require that the report to the healthcare provider include a recommendation that the healthcare provider perform a risk assessment.

(Response 94) The reporting requirements in this final rule are intended to promote clear communication about the results of the mammogram, not to prescribe other aspects of patient care. FDA acknowledges that risk assessments may be an important component of care for some patients; however, the Agency generally defers to healthcare providers to determine when a risk assessment is appropriate for their patients, and so declines to require that such an express recommendation be included in mammography reports. As noted in several other responses, the notification statements to patients with dense or non-dense tissue both say, in part, ''Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation'' (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that the interaction between patients and their healthcare provider presents an appropriate opportunity for the healthcare provider to assess the patient's individual risk factors.

(Comment 95) A comment asserts that most healthcare providers are not equipped to discuss potential options for further assessment with patients who are reported as having dense breasts.

(Response 95) FDA disagrees with this comment. Many resources related to breast density are available to healthcare providers from various sources such as professional societies, continuing education courses, and articles in professional journals (including, but not limited to Refs. 10, 12 to 14, 28, and 31 to 37), so healthcare providers should generally be equipped to discuss with patients potential options for further assessment.

(Comment 96) A comment asserts that there is little difference between heterogeneously dense breasts and extremely dense breasts, and that there is interobserver variability in assessing breast density.

(Response 96) FDA acknowledges that in some cases there may be interobserver variability in breast density assessment (*i.e.,* different IPs may assign different density categories to the same examination). However, we note that categorizing breast density is part of the IP's mammogram interpretation, and is not controlled by FDA. After the IP assigns a category, the final rule requires the category to be included in the mammography report, using the wording in this final rule (see § 900.12(c)(1)(vi)(A) and (D)), to promote clarity of communication between the IP and referring healthcare provider. We also note that the two categories of breast density cited by the commenter, which appear in § 900.12(c)(1)(vi)(C) and (D), respectively, as well as the other two categories in § 900.12(c)(1)(vi)(A) and (B), are already in wide use and conform to current clinical practice.

(Comment 97) A comment recommends that additional information and images regarding breast density be provided to clinicians and patients, and that FDA should consider providing, for clinicians, a reference to a specific article on breast density and the risk of interval cancer (Ref. 45).

(Response 97) FDA disagrees in part with this comment. Patients are not trained to interpret mammograms; the patient's referring healthcare provider is best suited to explain the mammogram results to the patient and provide additional information as needed. For healthcare providers, some references are cited in this final rule (including, but not limited to Refs. 10, 12 to 14, 28, 31 to 37, and 45) and healthcare providers can also identify additional resources such as medical journal articles, continuing education courses, or practice guidelines from professional societies that are most current or most relevant to the specific situation of the healthcare provider's patient.

L. Format for Image Interpretation, Retention, Transfer of Original Images, and Release of Copies

(Comment 98) A comment recommends clarification of the meaning and intent of the term ''original format'' as it relates to mammographic studies. Another comment recommends that digital images should not contain computer-aided detection (CAD) markings. A comment agrees with the proposed requirement to retain mammograms in the original modality in which they were obtained and not copied or digitized, and recommends that facilities be required to adhere to this requirement immediately upon publication of the rule rather than 18 months after publication of the rule.

(Response 98) We note that neither the proposed rule nor this final rule uses the phrase ''original format.'' The rule states that mammograms must be presented for interpretation in the ''original mammographic modality'' in which they were performed (see § 900.12(c)(1)), must be retained in retrievable form in the mammographic modality in which they were produced (see § 900.12(c)(4)(i)), and cannot be produced by copying or digitizing hardcopy originals (see § 900.12(c)(4)(i)). For mammographic images obtained by screen-film mammography, this means that the original films that were performed and used for interpretation must be retained, and they cannot be copied, scanned, or digitized to meet the record retention requirement. Mammographic images obtained by FFDM or DBT must be retained in digital format. In the rare situations in which FFDM images, which are produced in a digital format, are then printed and interpreted on hardcopy film, the facility may choose to retain this hardcopy print alongside the digital data, but if this hardcopy in turn is scanned or digitized, such scan cannot be the sole record of the examination that is retained. To ensure compliance with the requirement to maintain the original mammograms in § 900.12(c)(4)(i) and (ii), digital (FFDM or DBT) images must be retained such that the file format and all other characteristics of the original digital image files are preserved. Moreover, to ensure compliance with this requirement any CAD markings placed by computer software after the mammographic images are obtained, and which typically overlie and obscure portions of the image, must be removable and the images must be capable of being displayed without the CAD marks. A facility may choose to retain a set of the images with permanent CAD marks, but this set of images alone would not meet the retention requirement. FDA does not believe that these requirements should be effective earlier than the other provisions of the rule.

(Comment 99) Several comments recommend requiring facilities to store and transfer images in Digital Imaging and Communication in Medicine (DICOM) format. A comment recommends that DICOM be required so that proprietary file formats, which receiving facilities may not be able to view, are not used.

(Response 99) FDA disagrees with these comments. Although FDA acknowledges that DICOM is currently the predominant format used for image files in medical imaging, requiring the use of a specific file format in the MQSA regulations is overly restrictive and may limit the future development of alternative formats, including formats that offer improvements.

(Comment 100) Comments were received that recommend the use of lossy compression for digital mammogram images.

(Response 100) FDA disagrees with these comments. Section 900.12(c)(4)(i) of this final rule states that a facility ''Shall . . . maintain the mammograms and mammography reports in a permanent medical record of the patient'' for a specified time period, and § 900.12(c)(4)(ii) states that a facility ''Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly'' during this time period. Thus, the facility must retain the original mammogram, and must have it available for transfer upon request. Because lossless compression permits complete reconstruction of the image data, images undergoing such compression would be generally considered to be ''original'' mammograms for the purposes of § 900.12(c)(4) (this aligns with statements made by FDA in the PGHS (Refs. 46 to 48) regarding lossless compression of digital mammographic images). In contrast, images that have undergone lossy compression, which does not maintain all of the data related to the mammogram image files, would generally not be considered to be ''original'' mammograms for the purposes of § 900.12(c)(4). Transferring images that have undergone lossy compression would have potential consequences regarding the ability to process the digital mammogram files, and potential implications for the visualization of both normal tissue and abnormalities that may extend beyond the subjective image quality. While we acknowledge that data storage and transfer may pose significant considerations for facilities, we do not believe there is consensus on what loss of information is acceptable while maintaining the standards to be able to review and/or transfer the original mammogram images as required in the regulations.

(Comment 101) FDA received several comments that requested clarification on the conditions by which digital mammogram files are transferred between facilities, including the permissibility of downloading images from one facility to another, digitization of comparison images, and uploading of digital mammogram images from a compact disc (CD) to a receiving facility's picture archiving and communication system (PACS). A separate comment recommends that FDA require that mammograms be available for electronic transfer rather than by using physical media such as a CD. Another comment recommends that FDA develop a cloud-based or electronic repository of mammogram images for all MQSA-certified facilities.

(Response 101) Section 900.12(c)(4)(ii) and (iii) of this final rule address the transfer of original mammograms and release/provision of copies of mammograms, respectively. The Agency wishes to clarify its use of the terms transfer and release/provision of copies. In these regulations, ''transfer'' means the conveyance of the mammogram such that the sending facility no longer retains it. Screen-film examinations often are transferred; transfer of FFDM and DBT examinations is extremely rare because the original images are typically retained in the sending facility's PACS even when copies are released upon request. In the final rule, FDA distinguishes between ''interpretation'' (*i.e.,* initial, repeat, or additional review of a mammogram), for which an examination must be presented in the original mammographic modality in which it was performed (see § 900.12(c)(1) in this final rule), and ''comparison'' (*i.e.,* using a mammogram to aid in the interpretation of another exam), which is not subject to that requirement. Under the final rule, if transfer is requested, original mammograms must be transferred in the mammographic modality in which they were produced. Also, under the final rule, for interpretation purposes (including ''second opinion'' or additional interpretation), digital examinations must be presented to the IP in their

original digital modality. Thus, if a facility requests an FFDM or DBT examination in order to perform a second or additional interpretation at the request of the patient or their representative, the exam must be provided in its original modality (FFDM or DBT, respectively). We note that this may be accomplished either through transfer of the original images (which is rare), following the processes described in §§ 900.12(c)(4)(ii) and (iv) of this final rule, or through the release of a digital copy, following the processes described in § 900.12(c)(4)(iii) and (iv) of this final rule. FDA recognizes that many facilities may request the release of copies of mammograms not for interpretation of the requested exam, but for comparison purposes (*i.e.,* in order to aid the interpretation of a subsequent exam); such release must follow the processes described in § 900.12(c)(4)(iii) and (iv) (see also Response 102 below).

Technical methods of either transfer or release are not prescribed by the final rule, and may include, but are not limited to the following (assuming such transfers/releases otherwise comply with applicable law): direct electronic transmission of digital mammogram files that is arranged between two facilities utilizing Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant and appropriate practices for privacy and data security; providing the requesting facility with HIPAA-compliant remote electronic access to the images in the PACS of the originating facility; the viewing of digital mammogram images located on a physical storage medium such as a CD; or the uploading of such images from a digital storage medium to a receiving facility's PACS. FDA views all of these methods as meeting the requirement to provide original digital images electronically. FDA disagrees with the comment recommending that FDA require facilities to have the capability to electronically transmit original images or copies, rather than transmit via physical media such as CD–ROM, as FDA believes such a requirement may be overly burdensome and could impact a facility's ability to operate, which could reduce patient access to mammography services. We also disagree with the recommendation that FDA should develop and maintain a repository of mammogram images performed at all MQSA-certified facilities. We note that while such a repository could facilitate image comparison between facilities, there are significant privacy concerns, and also concern for the expense and resources required to establish and maintain such a repository. In addition, it may be excessively burdensome for facilities to participate in such a repository when facilities are already required to retain original mammogram images.

(Comment 102) A comment recommends that FDA develop a form asking if a facility is able to view hardcopy images, and a similar comment recommends that ''some consideration be given for facilities that no longer have equipment suitable for viewing hardcopy images.'' A comment also recommends that facilities should be required to transfer 2D images and images from other breast imaging modalities only, but should not be required to transmit DBT image sets due to their file size unless specifically requested.

(Response 102) FDA disagrees with the recommendation to develop a form regarding hardcopy viewing capability. As discussed in Response 101, this final rule includes different requirements when transferring original mammograms versus when releasing copies (see § 900.12(c)(4)(ii) and (iii) of this final rule). We reiterate that, in current practice, it is very rare for any facility to transfer a digital mammogram, whether FFDM or DBT. For these digital modalities, if a comparison is sought, typically only copies are provided, while the original images are retained by the performing facility, *i.e.,* they are not transferred. The requirements in this final rule are less stringent for the release of copies than for transfer of the original examination. Either original images or exact copies of digital exams may be used for interpretation (such as a second opinion) or comparison (see § 900.12(c)(1)). Copies of screen-film examinations may be used for comparison but not for interpretation (see § 900.12(c)(1)). However, FDA does not consider film copies of screen-film examinations to be in the original mammographic modality for purposes of § 900.12(c)(1), and thus such copies may be used for comparison but not for interpretation. As noted in Response 101, a facility may provide a digitized or scanned copy of a hardcopy original, such as a scan of a screen-film mammogram, either directly or via physical storage media. Therefore, a receiving facility that cannot view a hardcopy image may request a scanned or digitized copy for comparison purposes; the original film is only required if it is being submitted for interpretation, such as a second opinion. Note that this rule does not specify any requirement for the type of images that must be included when copies are released. Also, images from non-mammography imaging modalities are outside the scope of this rulemaking.

M. Deadlines for Image Transfer and the Release of Copies

(Comment 103) Several comments were received regarding ''transfer'' of comparison studies between facilities. A comment states that 15 calendar days is too long for a facility to transfer patient mammograms if a final report is required within 21 to 30 days. A comment notes that 15 calendar days is too accelerated a time for facilities to transfer large image files such as those associated with DBT image files when original images are requested for transfer. A comment agrees with requiring transfer of images within 15 days, but it recommends that FDA encourage facilities to transfer images within 7 days.

(Response 103) FDA generally disagrees with these comments. As noted in Responses 101 and 102, this rule distinguishes between transfer of original examinations and release of copies. For digital (FFDM and DBT) examinations, it is very rare to transfer the original; when comparison is sought, typically a copy is released. However, under this rule, the required timeframe is the same for either the transfer of originals or the release of copies, and therefore this response addresses both scenarios.

FDA believes that requiring the transfer of original mammogram studies, and the release of copies, within 15 calendar days of a request provides adequate time for a comparison to be made and a followup report to be issued (see § 900.12(c)(4)(ii) and (iii)), because the receiving facility will be aware of the deadline for issuing the final report, and can prioritize making the necessary comparison upon receiving the prior examination. FDA also notes that 15 days is the maximum amount of time allowed for a facility either to transfer original mammogram studies or to release copies, and is intended to be a baseline requirement, but we anticipate that the transfer or release will frequently occur in less than 15 days. FDA disagrees that 15 days is too little time for DBT studies to be transferred (or copies to be released) between facilities, despite the size of the image files, as the size of the file does not significantly affect the time required to provide electronic access to it, transmit it, or copy it. FDA believes that requiring the transfer of original examinations or the release of copies within 7 days may not allow adequate time for a facility to effect this transfer or release.

(Comment 104) A comment recommends that the 15-day requirement for the transfer of patient files be reconsidered since some records are faxed or mailed and would be difficult for a facility to track, and because there are already specific rules for medical recordkeeping, making this requirement redundant.

(Response 104) The 15-day deadline refers to the sending of (or provision of electronic access to) the requested records by the sending facility, not to their receipt by the receiving facility. FDA acknowledges that delivery time may be delayed by factors that are beyond the control of the sending facility, so the tracking time is not included in the required timeline. Given the importance of ensuring timely communication regarding final results of mammograms, FDA disagrees that a deadline for facsimile transmission or delivery of physical media is overly burdensome as to warrant the removal of this requirement from the regulations. Moreover, although there may be other applicable State and local medical recordkeeping requirements, such requirements are subject to change/repeal and there may be no requirements in certain States/localities. FDA believes it is important that there be consistent Federal regulations that clearly specify a timeframe in which a facility is required to transfer or release patient files, as this may have a significant impact on a patient's care and management.

(Comment 105) A comment recommends that FDA provide a guidance document that explains how a facility can demonstrate compliance with the records transfer and release requirements, including the method of determining the dates at which relevant actions occur.

(Response 105) We believe the records transfer and release requirements in this final rule, including the method of determining the dates at which relevant actions occur, are sufficiently clear. If facilities have specific questions about applicability to their situation, we believe such questions would be best addressed by directing the questions to FDA's MQSA Facility Hotline or the facility's AB.

N. Facility Closure and Mammography Record Retention

(Comment 106) A comment recommends that FDA create standard forms for use by closing facilities to communicate with patients and healthcare providers. Another comment recommends that the patients of a facility that closes or ceases mammography services should be notified, and a comment recommends defining the term ''reasonable efforts'' to be made in notifying affected patients.

(Response 106) Due to the variety of circumstances that may lead to the closure or cessation of mammography services at a facility, FDA believes that a standard form would not be feasible. This final rule requires that a facility that closes or ceases to provide mammography services notify its AB and certification agency of the arrangements that the facility has made, including making reasonable efforts to notify all affected patients (see § 900.12(c)(4)(v)). FDA believes this process will enable the AB and certification agency to assess the specific circumstances of the facility to help ensure that reasonable efforts are made by the facility to notify affected patients. Reasonable efforts may include, but are not limited to, sending written notification to patients using a traceable method, speaking directly to patients by telephone, or asking referring providers to reach those patients who the facility was unable to contact directly after attempting the above methods. However, FDA acknowledges the wide range of circumstances and unique factors that may be related to the reasonableness of a facility's efforts to notify all affected patients, and therefore this final rule requires the facility to discuss its notification efforts with its AB and certifying agency.

(Comment 107) A comment recommends that FDA include a requirement that before a facility closes or ceases performing mammography services, the facility must arrange for the permanent transfer of records to a facility that will provide access for at least 24 months.

(Response 107) FDA disagrees with this comment. Section 900.12(c)(4)(v) of the final regulations states that a facility that is closing or ceasing to perform mammography services must permanently transfer mammographic records to a patient or the patient's healthcare provider, or transfer the mammographic records to another facility or entity that will provide access to those records for the patient or the patient's healthcare provider for the time periods specified in § 900.12(c)(4)(i), which are longer than 24 months. Because mammography records can be of continuing value to a patient's care, the Agency believes that they should remain accessible for the same length of time whether they were performed at a facility that continues to perform mammography or whether they were performed at a facility that has closed or ceased to perform mammography. Therefore, the time periods for retention specified in § 900.12(c)(4)(i) apply from the date of performance of the exam at the facility through the time after records are transferred from facilities that close or cease to perform mammography to another facility or entity that will provide access to patients and healthcare providers (see § 900.12(c)(4)(v) of this final rule).

FDA also believes that if a mammography facility that is part of a medical entity such as a radiology practice or hospital ceases to perform mammography, but the medical entity does not close, the medical entity may be able to continue to retain and release the mammography records in a manner consistent with the requirements in § 900.12(c)(4)(i) through (iv). Accordingly, we are revising the proposed requirement that a facility must make arrangements for access by patients and healthcare providers to their mammographic records before the facility closes or ceases to provide mammography services, in § 900.12(c)(4)(v), to add that ''If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of § 900.12(c)(4)(i) through (iv), it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient.''

O. Mammography Medical Outcomes Audit

(Comment 108) Several comments recommend that FDA provide additional guidance regarding the medical outcomes audit, including clarification of the definition of a positive study, specifying which method should be used to calculate the PPV, and differentiating between screening and diagnostic mammogram studies when calculating PPV. Related comments recommend the use of a patient's screening interval, which may or may not be 1 year, as the time period over which to calculate PPV, and updating the definitions of positive and negative studies in the MQSA implementing regulations to conform to the definitions in the ACR BI–RADS 5th edition (Ref. 49).

(Response 108) In § 900.2(mm), a positive mammogram is defined as a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.'' This definition was used in the discussion of the metrics for the outcomes audit within § 900.12(f). The MQSA and its implementing regulations

apply to all mammograms, including those performed for either screening or diagnosis. In this final rule, only for the purposes of calculating the audit metrics, FDA has acknowledged the distinct clinical roles of screening mammography and diagnostic mammography. For clarification, in this final rule we are replacing the phrase ''For the purposes of these requirements'' in the medical audit outcomes provision with the phrase ''For the purposes of these audit requirements'' (see § 900.12(f)(1) in this final rule).

We note that the clinical practice community recognizes several different methods for calculating the PPV, including the PPV1, PPV2sc, PPV2dx, and PPV3 (Refs. 49 and 50.). Of these variants, the PPV2sc includes the outcomes of all biopsy recommendations, whether that recommendation resulted directly from a screening mammogram (a sequence that is clinically discouraged (Ref. 49) and rarely occurs in practice) or from a subsequent diagnostic mammogram performed after an abnormal screening mammogram. As stated in § 900.12(f)(1)(i) in this final rule, FDA will require facilities to calculate the PPV as the percent of patients with positive mammograms who are diagnosed with breast cancer within 1 year of the date of the mammographic examination. This metric is essentially identical to the PPV2sc used by the clinical practice community, and uses a 1-year interval like the PPV2sc. The use of this metric is considered a minimum requirement; facilities are also permitted to calculate additional PPVs using other methods if they choose to do so. However, FDA disagrees with the recommendation to adopt definitions from a particular edition of a particular clinical practice guideline, to avoid restricting the future development of mammography practice.

(Comment 109) Several comments also recommend clarification of the definition of cancer detection rate (CDR) and recommend separate calculations for CDR for screening and diagnostic mammogram studies.

(Response 109) FDA recognizes that the clinical practice community uses various methods for calculating CDR, including calculating CDR only for screening mammograms, or separately for screening and diagnostic mammograms. The CDR calculation required by this final rule (see § 900.12(f)(1)(ii) in this final rule) is a single calculation for CDR for screening mammograms. As with Response 108, regarding PPV, the calculation method for CDR in this final rule is also considered a minimum requirement. Facilities are permitted to calculate CDR using additional methods if they choose to do so. However, FDA also notes that the PPV required by § 900.12(f)(1)(i) of this final rule is essentially equivalent to the CDR calculation for diagnostic mammograms, so by meeting the requirements of this final rule, facilities will be calculating both the CDR for screening mammograms and a value (*i.e.,* PPV) using a calculation that is essentially equivalent to the calculation done for the CDR for diagnostic mammograms.

(Comment 110) A comment states that in BI–RADS, a screening mammogram assessed as either category 0, 3, 4, or 5 (*i.e.,* Incomplete, Probably Benign, Suspicious, or Highly Suggestive of Malignancy, respectively) is considered positive, and may be suggesting that FDA adopt this approach.

(Response 110) This final rule states that recall rate will be calculated as the percentage of screening mammograms given an assessment of ''Incomplete: Need additional imaging evaluation'' (see § 900.12(f)(1)(iii)). We note that assigning any of the other assessments mentioned by the commenter—Probably Benign, Suspicious, or Highly Suggestive of Malignancy—to a screening mammogram is clinically discouraged (Ref. 51) and rarely occurs in practice.

(Comment 111) Several comments recommend that FDA offer further guidance on how facilities should interpret medical outcomes data and derive performance data. A comment recommends linking the medical outcomes data with cancer registries.

(Response 111) The medical outcomes audit is intended to allow each facility to assess and improve its own performance. FDA's finalized metrics of PPV, CDR, and recall rate for the outcomes audit are minimum requirements; facilities are not restricted from calculating additional metrics if they choose to do so. Regarding the recommendation to link medical outcomes data with cancer registries, this is outside the scope of this rule, although the regulations do not prohibit facilities from adopting this practice.

(Comment 112) Comments recommend that mammograms used for localization should have no numeric value and should be excluded from medical outcomes audits.

(Response 112) FDA agrees that mammograms used for localization should be excluded from the medical outcomes audit, and the required calculations in § 900.12(f)(1)(i) through (iii) in this final rule do not include mammograms that are in this category. As noted in Responses 38 and 108, only a mammogram that receives an overall assessment of either ''suspicious'' or ''highly suggestive of malignancy'' is defined as a positive mammogram (see § 900.2(mm)). This final rule adds the assessment category ''Post-Procedure Mammogram for Marker Placement'' (see § 900.12(c)(1)(iv)(G)), which may be assigned in the clinical scenario described in this comment. If a mammogram receives the assessment ''Post-Procedure Mammogram for Marker Placement,'' rather than the positive assessment of ''suspicious'' or ''highly suggestive of malignancy,'' then it is not a positive mammogram, and should not be counted in any audit calculations that track the outcomes of positive mammograms.

FDA also reiterates that all of the assessment statements in the MQSA regulations are comprised exclusively of words or phrases, as noted in Response 35, and do not include numeric values or codes (see § 900.12(c)(1)(iv) and (v) of this final rule); code numbers are used together with assessments in some clinical practice guidelines, such as ACR BI–RADS, but are not part of the approved assessment statements.

(Comment 113) A comment recommends maintaining the current medical outcomes audit requirements, as the comments states that additional requirements in the proposed regulations will result in inspection failures at facilities with limited resources.

(Response 113) FDA disagrees with the comment. The Agency believes that it is appropriate to provide the additional requirements for the medical outcomes audit that are included in this final rule (see § 900.12(f)(1)). The three additional metrics in this final rule are widely acknowledged in the clinical practice community and are already in wide use in mammography practices. Because all certified facilities already perform a medical outcomes audit, which for many facilities already includes these specific metrics, we believe that adding these metrics to the requirements will not be unduly burdensome. Also, we note that although MQSA inspectors will check whether each facility is performing these calculations, those inspectors generally will not document the specific values obtained by the audit.

(Comment 114) Several comments recommend additional clarification regarding the medical outcomes audit, including how it relates to annual facility inspection, how long it should be retained, and who has access to the audit.

(Response 114) During a facility's annual inspection, the inspector generally will verify that a facility has completed its medical outcomes audit during the time period for which the annual inspection is evaluating the facility, or (in the event the inspection occurs during the first 2 years of the facility's operation) will verify that the facility has established the required audit procedures and designated an audit IP (Ref. 18). This final rule requires that facilities, at a minimum, calculate the PPV, CDR, and recall rate (see § 900.12(f)(1) in this final rule), and the inspector generally will check whether these three metrics, at a minimum, have been calculated, or that the procedures for calculating them are in place, as applicable. However, FDA does not anticipate that the inspector will document the specific values obtained by the medical outcomes audit. The inspector will generally verify that the audit IP has notified each IP at the facility of their respective individual audit results and the facility's aggregate results, or, in the event the inspection occurs during the first 2 years of the facility's operation, generally will verify that the facility has established a procedure for such notification. The inspector generally will also verify that the audit IP has documented any followup actions taken, or that the facility has established a system for such documentation. Because the audit information is subject to inspection, at a minimum, the data must be retained by the facility until the MQSA inspection that covers that medical outcomes audit (see § 900.12(f)(4)). After the MQSA inspection that covers that medical outcomes audit, the facility and the audit IP may determine any ongoing utility of the medical outcomes audit data, and may elect a longer retention time if this is deemed beneficial to the facility. As noted, § 900.12(f)(3) requires that each IP be notified of that IP's respective individual audit results and the facility's aggregate results; beyond this requirement, the facility and the audit IP can determine who else, if anyone, may have access to the data.

P. Patient and Referring Provider Notification

(Comment 115) A comment recommends that FDA and the State certification agency be required to directly notify patients and providers, and that they may use mass media only if all other options for direct notification have been exhausted, for PPNs, when a facility is not able or willing to perform the PPN.

(Response 115) FDA disagrees with the comment. The Agency notes that some facilities that have been required to perform a PPN have reported that they were unable or unwilling to do so, but the circumstances of each facility differed. This provision of the rule (see § 900.12(j)(2) of this final rule) expressly states that FDA or a State certification agency may notify the affected population if a facility is unable or unwilling to perform such notification. The requirement recommended in the comment could cause significant delays in notification of affected patients and their providers, related to both the attempt to identify all possible options and the practical considerations of performing individual notification. If a facility is unable or unwilling to perform a required PPN, FDA intends that State certification agencies and FDA will act in the manner that best serves the interests of public health and will consider the specific circumstances when selecting the method(s) for notification of patients and healthcare providers.

(Comment 116) A comment recommends that the description of non-physician healthcare providers in § 900.12(j)(2) (*i.e.,* ''other healthcare providers''), in the context of PPNs, be included earlier in the final regulations.

(Response 116) FDA agrees with the comment. The reference to non-physician healthcare providers in § 900.12(j)(2) in this final rule revises this specific provision in the 1997 MQSA final rule (62 FR 55852), which previously listed only patients and their referring physicians as parties who must be notified in the event of a PPN. This revision is intended to address notification of non-physician referring providers when their patients are among the affected PPN population. However, we agree that some earlier references in the regulations to referring physicians should also be revised to use or incorporate the term ''healthcare provider.'' In this final rule, FDA is either replacing the word ''physician'' with the term ''provider'' or ''healthcare provider,'' or adding one of these terms in addition to ''physician,'' in §§ 900.2(c)(2), 900.2(k), 900.2(ii), 900.4(f)(1)(ii)(B), and 900.12(j). Some other sections of the regulations already use the term ''provider,'' and FDA believes that this term in those instances remains accurate (see §§ 900.12(c)(1)(vi), 900.12(c)(2)(i) and (ii), 900.12(c)(3), 900.12(c)(3)(i) and (ii), 900.12(c)(4)(ii)).

Q. Revocation of Certification

(Comment 117) A comment recommends using boldface text to state that a State agency that is an FDA-approved State certification agency (SCA) under the States-as-certifiers provision may suspend or revoke a certificate.

(Response 117) FDA understands the concern for readability of the regulations; however, FDA is unable to change the typeface and font used for display and printing of regulations in the CFR, as such stylistic issues are determined by the U.S. Government Publishing Office for the entire Federal government. For clarification, part 900, subpart C (''States as Certifiers'') establishes the procedures for a State to apply to become an FDA-approved SCA, and the requirements and standards for the SCA to use to ensure that all mammography facilities are adequately and consistently evaluated for compliance with quality standards at least as stringent as those established by FDA. SCAs are required to have appropriate criteria and processes for suspension and revocation of certificates and to have a process for appeals of inspection findings, enforcement actions, and adverse certification decisions (§ 900.22(d) and (e)). SCAs cannot suspend or revoke certificates under the authority in § 900.14, but instead are required to have their own process for taking such actions.

(Comment 118) A comment recommends that FDA define an operator of a facility.

(Response 118) FDA disagrees with this recommendation. The exact role, responsibilities, and title of an operator varies depending on the specific circumstances of the individual facility and operator. Operators may include the lead IP, other IPs, QC technologist, other radiologic technologists, medical physicists, or other staff, depending on the circumstances. Operators may have varied responsibilities, including but not limited to ensuring that a facility's quality assurance program meets the requirements set forth in this final rule, interpreting mammograms, evaluating the performance of mammography equipment, positioning patients for radiographic examinations, or performing other staff responsibilities at a facility.

(Comment 119) A comment recommends that a facility that has had its certificate revoked should not return to practice without probationary oversight.

(Response 119) FDA disagrees with this recommendation. Before a facility whose certificate was revoked can return to the practice of mammography, it will have to comply with all corrective actions required by its AB. Additionally, under the MQSA, when a facility's certificate is revoked, the owners and operators of the facility at

the time of the revocation may not own or operate a mammography facility for 2 years (42 U.S.C. 263b(i)(3)). At the end of those 2 years, those operators will have failed to maintain their qualifications under the MQSA and implementing regulations, and will be required to reestablish qualification, each according to the requirements for their profession (either § 900.12(a)(1)(iv) for IPs; §§ 900.12(a)(2)(iii)(D) and 900.12(a)(2)(iv)(B) for radiologic technologists; or § 900.12(a)(3)(iv) for medical physicists) before they may resume practice at a certified facility. FDA thinks that the facility and its operators will have received sufficient training and completed sufficient corrective action before they are permitted to return to practice. Furthermore, upon returning to practice, the facility and personnel again become subject to all accreditation and certification requirements of the AB and FDA (or SCA).

R. Interpreting Physician Qualifications, Including Continuing Experience

(Comment 120) Several comments were submitted regarding the continuing experience and continuing education requirements for IPs. Comments recommend: (1) increasing the number of mammographic examinations that an IP must interpret to satisfy the continuing experience requirement; (2) adding a requirement for a minimum number of diagnostic mammograms that must be read; (3) requiring continuous feedback to IPs on individual cases rather than only at the time of the annual medical outcomes audit; (4) requiring that IPs ''work up'' their own recalled cases; and (5) requiring that IPs at facilities with lower volumes and in low-income areas be exposed to more mammography examinations.

(Response 120) (1) Regarding the number of mammographic examinations an IP must interpret to satisfy the continuing experience requirement, although FDA acknowledges that there may be certain benefits to increasing the continuing experience requirement, this must be weighed against a potential loss in access to mammography services if IPs are unable to satisfy these increased requirements. FDA believes that the current continuing experience requirements, as described in § 900.12(a)(1)(ii), represent a reasonable balance between the goals of maintaining an IP's ongoing ability to interpret mammograms and preserving access to mammography services at facilities across the country.

(2) Regarding an additional requirement for a minimum number of diagnostic mammograms versus screening mammograms, FDA again believes that while there may be certain benefits with such a requirement, establishing such a requirement may adversely impact the ability of IPs who work in varied settings to meet these requirements and to continue interpreting mammogram studies, again potentially impacting access to mammography services. Furthermore, as noted in Response 108, with the exception of the outcomes audit requirements (see § 900.12(f) in this final rule), the MQSA regulations do not distinguish between mammograms performed for screening or diagnosis.

(3) Regarding the recommendation for requiring continuous feedback on individual cases to IPs, FDA notes that there is a requirement in § 900.12(i) that ''[c]linical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.'' To ensure compliance with such standards, facilities conduct regular periodic reviews of the image quality of samples of the images performed by each RT and the images accepted for interpretation by each IP (see Ref. 52). This is a mechanism for providing periodic image quality feedback to IPs. The Agency believes that this requirement, together with the requirement to provide IPs with outcomes feedback from the annual medical outcomes audit and the requirements for continuing education and continuing experience are reasonable and appropriate to ensure an IP's ongoing ability to interpret mammographic examinations.

(4) Regarding the recommendation that IPs be required to work up their own recalled cases, FDA notes that workflow as well as personnel schedules vary across facilities; also, some facilities perform only screening and not diagnostic mammograms. Therefore, we believe that such a requirement would be significantly burdensome for facilities to implement, and may be both impractical and restrictive for scheduling, both for the IP and for the patient, which could lead to decreased access to mammography services.

(5) Regarding IPs at lower volume facilities or in areas with a low-income population, such IPs are required to meet the continuing experience requirements (see § 900.12(a)(2)(ii)). FDA believes that placing additional requirements on IPs at these facilities would be detrimental to these facilities' ongoing ability to operate and provide services to their patient populations. As with other MQSA requirements, the continuing experience requirement is a baseline national standard; the MQSA regulations do not prohibit IPs from obtaining additional experience nor facilities from requiring that their employees obtain additional experience.

(Comment 121) A comment recommends that continuing education be specifically required to be obtained through active, case-based learning, and test sets with feedback.

(Response 121) FDA disagrees with the comment, and so has not incorporated this requirement in the final rule. FDA believes that the continuing education requirements for IPs, as described in § 900.12(a)(1)(ii)(B), are appropriate and adequate to ensure the ongoing education of IPs in mammography. Adding specific requirements such as those recommended by the commenter may be overly burdensome, risking a decrease in personnel and in patient access to mammography services. FDA also notes that specific requirements for active, case-based learning and for test sets with user feedback may be confusing to IPs and facilities determining how to satisfy such requirements.

(Comment 122) A comment recommends that double-reading be required for some IPs, such as newly trained IPs, requalifying IPs, or those who do not meet benchmarks.

(Response 122) FDA disagrees with the comment, and has not added this requirement in the final rule. FDA believes that the requirements for initial qualification of IPs, as described in § 900.12(a)(1)(i), and for requalifying IPs, as described in § 900.12(a)(1)(iv), are adequate, and in both of these situations, there is already a requirement for interpretation of certain numbers of mammograms under the direct supervision of a qualified IP. The MQSA and part 900 do not contain specific benchmarks for the performance of IPs in the interpretation of mammograms, and while we note that careful review of the results of the annual medical outcomes audit may be beneficial for IPs and informative in guiding their selection of continuing education to address areas where improvement is needed, we do not agree that it is necessary to introduce a requirement for additional supervised interpretation for qualified IPs.

S. Cleaning of Mammography Equipment

(Comment 123) A comment recommends that the MQSA regulations be more specific regarding when and how mammography equipment should be cleaned.

(Response 123) FDA disagrees that more specificity is needed in these regulations regarding this issue. The regulations already describe processes that facilities must follow regarding cleaning and disinfecting mammography equipment (see §§ 900.12(e)(11)(ii) and 900.12(e)(13)). The Agency is not aware of information showing that the existing requirements have led to contamination of equipment. This final rule does not provide additional requirements beyond those already specified because we believe that these requirements are adequate in their detail regarding the cleaning and disinfecting of mammography equipment.

T. Availability and Clinical Role of Breast Imaging Modalities, Screening Mammography Guidelines

(Comment 124) A comment recommends that facilities should be required to offer 3D mammography (*i.e.,* DBT) and ultrasonography within 6 months of publication of this final rule; another comment recommends that facilities should be required to offer DBT within 10 years of publication of this rule; and a comment recommends that every mammography facility should be required to have at least one 3D mammography unit. A different comment suggests that a list of facilities offering advanced technologies, including 3D mammography, should be published.

(Response 124) FDA disagrees with these comments. Various devices cleared or approved by FDA are respectively capable of performing examinations using different mammographic modalities, including screen-film, FFDM, and DBT; the choice of the specific technology used to image each patient is a decision by the IP and the patient's referring healthcare provider, if any. FDA does not require facilities to offer specific equipment or particular imaging modalities. Additionally, as stated in the proposed rule, Executive Summary section I.A, the MQSA and implementing regulations are designed to ensure that all patients nationwide have access to quality mammography services, and FDA is concerned that instituting a requirement to use only more expensive technology (*e.g.,* DBT) may place a significant financial burden on facilities, potentially impacting their ability to operate, which may then reduce patient access to mammography services. Regarding the recommendation to publish a list of facilities offering 3D mammography, FDA does offer a public database of all certified facilities (Ref. 53), but the Agency thinks that including information on the equipment at each facility would be impractical, as equipment changes at facilities may occur at irregular and potentially frequent intervals, including both the introduction and removal of equipment, which may impact the accuracy of the information in such a list.

(Comment 125) Many comments recommend the use of specific medical imaging technologies, including 3D mammography and other modalities such as ultrasound and MRI, in varying clinical situations for the examination of patients with dense breasts. Specifically, several comments recommend that women with dense breasts should either have only 3D mammography performed, or have both 3D mammography and ultrasound performed, with a comment recommending that mammography and ultrasound should be performed every 3 months, or that imaging modalities other than mammography should be used. A comment recommends that information regarding the benefits of 3D mammography be provided to patients. Conversely, another comment recommends that 3D mammography be pulled from use until additional safety and efficacy studies have been performed due to its higher radiation dose compared to 2D imaging. Another comment recommends that patients be provided with information on ultrasound and that women should be able to choose to have either a mammogram or an ultrasound.

(Response 125) FDA disagrees with incorporating these recommendations into the regulations. Certain 2D and 3D (*i.e.,* DBT) mammography equipment has been approved or cleared by FDA following FDA's review of a premarket approval application or premarket notification (510(k)) submission. The choice of particular breast imaging modalities or screening time intervals, whether for patients with dense breasts or for any other patients, is a decision for healthcare providers to make in caring for their patients. Likewise, we defer to healthcare providers on provider-patient discussions regarding use of ultrasound or other tests when caring for their patients.

(Comment 126) Several comments recommend that providers be notified of the possibility that additional imaging modalities may be needed.

(Response 126) The consideration of the benefits, risks, and uses of various tests or imaging modalities is most appropriately left to the licensed healthcare provider. We decline to incorporate this recommendation.

(Comment 127) Several comments recommend that patients be informed of other options for breast imaging such as molecular breast imaging (MBI), ultrasound, and MRI. A comment also recommends that patients be informed that their health insurance plan may not cover these tests.

(Response 127) FDA disagrees with adding a requirement to the regulations to inform patients of other options for breast imaging, including because the options for breast imaging may change with technological advancements. The required density notification language in the final rule includes a recommendation that all patients discuss their individual situation with their healthcare provider (see § 900.12(c)(2)(iii) and (iv)), and advises patients with dense breasts that in some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers (see § 900.12(c)(2)(iv)). Insurance coverage and reimbursement are outside the scope of these regulations; furthermore, FDA is also concerned that including references to insurance coverage in the lay summary may distract from the information in the breast density notification.

(Comment 128) Several comments suggest that MBI should be recommended to patients, be added to a list of supplemental screening methods, or have information about it provided to patients.

(Response 128) FDA believes that decisions about the use of various imaging modalities, including whether or not to consider them, are more appropriate for the healthcare provider to make, as they can take into consideration their understanding of the specific patient and the patient's needs from their relationship with the patient and medical history.

(Comment 129) A comment recommends that FDA approve thermography and ultrasound used together as an alternative to mammography.

(Response 129) As we noted in various responses, the MQSA applies only to mammography activities. Accordingly, breast sonography and thermography are both outside the scope of this rulemaking and are both outside the scope of the MQSA. Additionally, FDA has issued a Safety Communication (Ref. 54) and a Consumer Update (Ref. 55) that warn that thermography is not an effective alternative to mammography, and that there is no valid scientific data to demonstrate that thermography devices, on their own or with another diagnostic test, are an effective screening tool for any medical condition, including the early detection of breast cancer. People who choose thermography instead of

mammography may miss the chance to detect breast cancer at its earliest and most treatable stages.

U. Clinical Decision-Making

(Comment 130) A comment recommends that healthcare facilities be required to arrange mammography appointments for patients on the same day that a clinical breast exam is performed. Another comment recommends that healthcare providers be required to schedule followup appointments with patients reported to have dense breasts, and a comment recommends that physicians use shared decision-making with their patients. Several comments recommend that IPs be able to assume the role of healthcare provider for a patient with no referring provider, and that the IP should be able to order additional imaging studies such as ultrasound. A comment also recommends that patients be able to self-refer for supplemental breast imaging.

(Response 130) FDA agrees that providing timely breast imaging services to patients is important. However, the scope of the MQSA is limited to the regulation of mammography facilities and their activities (see 42 U.S.C. 263b(a)(3)), as opposed to regulation of more general healthcare provider practices, such as the ordering of imaging studies or general followup with patients by their primary care physician or referring provider. Radiologist ordering of additional imaging studies and patient self-referral for imaging are both largely dependent on State or local requirements or specific facility policies and are outside the scope of this rulemaking (see also Responses 70, 89, 90, 125, and 131).

(Comment 131) A comment recommends that breast imaging centers should not refuse to perform annual mammography on patients with dense breasts. A comment recommends that facilities should interpret mammograms in real time and add ultrasound for patients with dense breasts. Another comment recommends that radiologists use all available technologies to determine breast density.

(Response 131) The MQSA regulations do not take a position on the frequency or interval for screening mammography, as these vary and FDA generally defers to healthcare providers on such matters involving clinical decision-making with their patients. Similarly, other than the requirement to issue the report and lay summary (following interpretation of the mammogram) within respectively specified time periods (see § 900.12(c)(2) and (3) in this final rule), the timing and workflow for the interpretation itself is generally outside the scope of this rule. FDA notes that imposing a requirement to interpret examinations in real time may be overly burdensome to many facilities and may impact their ability to operate, thus reducing patient access to mammography services. The recommendation to require facilities to add ultrasound or other non-mammographic breast imaging modalities is outside the scope of authority of the MQSA, and is addressed in responses to other comments (see Responses 2, 4, 6, 41). FDA also concludes that a requirement for facilities to use all available technologies, or any particular technology, to determine breast density is overly burdensome and would unnecessarily restrict facilities both in terms of the resources and time required to acquire the equipment and to implement such a requirement. Also, the MQSA regulations do not require the use of specific devices; similarly, no AB is permitted to require the use of specific devices or products as a condition of accreditation (see § 900.4(a)(5)).

(Comment 132) Comments recommend that mammography patients should be informed of the limitations and radiation risk of mammography and asked to provide consent prior to undergoing mammography, and that patients should be informed of the risk of overdiagnosis and overtreatment of breast cancer due to screening mammography.

(Response 132) As noted in Response 131, the clinical indications used to decide when to perform a mammogram are more appropriate for the referring healthcare provider to consider. FDA notes that the healthcare provider who refers a patient for a mammogram can discuss with that patient the benefits and risks of the examination, including the implications of the potential results, and the patient and provider can utilize shared decision-making to determine whether to proceed with the examination. Additionally, although not addressed in the MQSA or its implementing regulations, a critical component of FDA premarket approval or clearance of any mammography equipment is a benefit-risk analysis that considers the radiation exposure associated with imaging with the device, among other information, before determining that the device meets the standard for approval, clearance, or marketing authorization when used according to its stated indications (Ref. 56).

(Comment 133) A comment recommends that all mammograms should be performed as screening mammography.

(Response 133) The MQSA was passed to improve the quality of mammography, regardless of the clinical scenario in which a particular mammogram is recommended or performed. With the exception of the medical outcomes audit, as discussed in § 900.12(f)(1) in this final rule, the MQSA and its implementing regulations do not distinguish between screening and diagnostic mammography. As we noted in Response 131, the choice of a screening time interval and other clinical decisions related to mammography are more appropriate for the healthcare provider in the course of clinical decision-making with the patient.

V. Insurance Coverage

(Comment 134) Many of these comments recommend the following: (1) insurance should cover all breast imaging services, including mammography, MRI, ultrasound, and breast biopsy procedures; (2) insurance should be required to reimburse for ''3D breast imaging'' (this term is not specific, but the commenter may be referring to DBT, which is a mammographic modality subject to MQSA); (3) insurance coverage should not be impacted by a patient having dense breasts; (4) insurance coverage should be mandated such that socioeconomic disparities in treatment and outcomes will not be worsened; (5) additional reimbursement per examination should be granted to facilities in rural and underserved areas to cover the cost of new equipment; and (6) genetic testing and patient education should be provided at no additional expense to the patient. Another comment suggests that FDA should limit the interest rate charged by equipment manufacturers for facilities that finance equipment purchases from them. Finally, several comments recommend requiring insurers, including Medicare/Medicaid, to increase reimbursement for screening mammography and to eliminate patient expense for annual mammograms for patients aged 40 to 74 years and for high-risk patients aged 25 to 40 years.

(Response 134) FDA considers the recommendations within these comments to be outside the scope of its authority to regulate under the MQSA or other authorities. We recognize that healthcare costs are a significant concern to the public. FDA recommends that patients check with their insurance company regarding coverage before

undergoing mammography examinations.

W. Economic Impact of This Rule

(Comment 135) A comment asserts that the costs associated with MQSA are high, and recommends that a less expensive way be found to encourage and mandate that facilities use ''decent'' equipment and personnel.

(Response 135) To the extent the comment is about the cost of the proposed rule, FDA disagrees with the comment. As discussed in the proposed rule and elsewhere in this final rule, we considered costs and benefits. We conclude that the current final rule represents an appropriate balance between costs and benefits, with the goal of improving mammography quality and the public health.

(Comment 136) One comment expresses support for the modernization of the MQSA regulations, but states that the ''breast x-ray examination fee is relatively high in the proposed rules, which ranges from $600 to $1,800,'' and recommends that the regulations provide examination methods that are less expensive than mammography.

(Response 136) FDA appreciates the commenter's support for the regulations. We note that the commenter misunderstood the preliminary economic analysis, which estimated at between $615.44 and $1,819.96 the present value of the costs to each facility to implement the changes to the MQSA regulations; these costs do not represent a fee charged to a patient undergoing a mammogram. Furthermore, as we noted in Response 134, issues of insurance coverage and reimbursement are outside the scope of FDA's authority.

(Comment 137) Several comments state that the benefits estimated in the Preliminary Regulatory Impact Analysis related to fatalities and cost savings due to density reporting are not supported by existing evidence, and that the estimates of costs of overtreatment and overdiagnosis are omitted from the analysis.

(Response 137) Recent research has shown that 7 percent to 11 percent of patients who are informed that they have dense breasts undergo supplemental ultrasound screening (Refs. 57–59). Research studies have also shown that adjunct ultrasound screening in high-risk women with dense breasts results on average in the detection between 2.75 to 3.90 additional cancers per 1,000 women (Refs. 11, 32, and 60 to 62). Because survival rates are higher for cancers detected at an earlier stage, early cancer detection due to supplemental screening such as ultrasound for women with dense breasts may result in a reduction in cancer fatalities. We use this existing evidence to support our analysis related to quantified benefits of breast density reporting requirements. These potential outcomes are discussed qualitatively in the Final Regulatory Impact Analysis (FRIA) (Ref. 63). Additionally, the density notification requirement does not discuss additional clinical management beyond imaging. We believe that a discussion of overtreatment and overdiagnosis of cancer is outside the scope of this rulemaking, and so have not been addressed by this analysis.

(Comment 138) A comment suggests that the analysis be revised to include distributional and equity effects.

(Response 138) FDA recognizes that distributional and equity considerations may exist as they relate to mammography practice and density notification. We have revised the distribution section of the FRIA to include a qualitative discussion of sociodemographic differences in mammography practice and outcomes.

X. Federalism and the Relationship Between Federal and State Breast Density Reporting Requirements

(Comment 139) Some comments recommend that FDA clarify the relationship between Federal and State breast density requirements, and specifically: (1) whether facilities must always use the Federal breast density notification language and (2) whether the Federal breast density notification requirements preempt State requirements. If there is preemption, a comment states that FDA should consider whether it has adequate evidence to justify such preemption, consistent with Executive Order 13132 (Ref. 64). Some of the comments submitted regarding preemption seem to be addressing express preemption, whereas others seem to be addressing implied preemption.

(Response 139) With regard to the first question, all facilities providing mammography services will be required to comply with FDA's reporting requirements, regardless of whether there are applicable State requirements. Under § 900.12(c)(1)(vi), (c)(2)(iii), and (iv), facilities must provide the breast density information specified in those regulations in mammography reports to healthcare providers and in lay summaries to patients. The regulations do not include exceptions for facilities in States with breast density reporting requirements. As discussed in Response 140, FDA believes these requirements are critical, among other things, to ensuring that patients and healthcare providers receive accurate, complete, and understandable breast density information.

With regard to the second question, Federal law can expressly preempt State law when the text of a Federal statute explicitly manifests Congress's intent to displace state law. Federal law also can impliedly preempt State law when Congress's preemptive intent is implicit in the relevant Federal law's text, structure, and purpose. Courts have identified two subcategories of implied preemption—field preemption and conflict preemption. Field preemption occurs when a comprehensive scheme of Federal regulation implicitly precludes supplementary State regulation. Conflict preemption occurs when simultaneous compliance with Federal and State law is impossible (''impossibility preemption'') or when State law poses an obstacle to the accomplishment of Federal goals (''obstacle preemption'').

Here, Congress included a preservation provision addressing State laws, which provides: ''Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.'' (42 U.S.C. 263b(m)). Thus, the statute preserves any State law that is ''at least as stringent'' as the regulations issued by FDA under the MQSA. See also 138 Cong. Rec. 33615 (October 7, 1992) (''The bill allows and encourages states to carry out the certification program requirements and to implement standards no less stringent than those of the national program.'').

Based on the preservation clause of the MQSA, FDA's reporting requirements do not preempt State reporting requirements that are ''at least as stringent'' as the Federal requirements. The provisions of the MQSA, however, do not resolve which State reporting requirements, if any, that are less stringent than the Federal requirements may be subject to preemption. That analysis would be informed by the specific provisions of the State laws in question, and FDA has not undertaken a 50-state analysis of all current State breast density reporting laws. We note, however, that it is possible for a State breast density reporting law to be preempted based on these regulations. For example, if a State law theoretically were to prohibit facilities from providing a breast density notification to patients with non-dense breasts, we believe that law could be preempted because it would be impossible for facilities to comply with

both the Federal law (which requires such breast density reporting) and the State law (which forbids it). As another example, if a State were to require a breast density statement that directly contradicts or undermines a key message in FDA's breast-density reporting requirement (such as the message that ''dense tissue makes it harder to find breast cancer on a mammogram,'' or ''dense tissue . . . raises the risk of developing breast cancer,''), that State law could be preempted on the basis that it poses an obstacle to the accomplishment of FDA's goals in communicating clear, consistent, and understandable information about breast density to patients and healthcare providers.

For further discussion of this final rule and the federalism principles expressed in Executive Order 13132, please see other responses in section X.

(Comment 140) Several comments express concern with having potentially two different breast density notifications for patients and their healthcare providers, one required by Federal law and one required by State law. The comments note that different notifications could lead to patient confusion and be overly burdensome for facilities. For these and related reasons, some comments recommend that FDA include a clear statement that the Federal breast density reporting requirements preempt State requirements, while other comments recommend that FDA not require Federal breast density reporting language and allow State language to be used instead, at least in certain circumstances (*e.g.,* so long as certain information is included in the notification). One comment proposes that FDA develop a ''waiver'' process to allow the State to apply to FDA to use its alternative notification.

(Response 140) FDA declines to adopt these recommendations. As previously explained, all facilities providing mammography will be required to comply with FDA's reporting requirements, regardless of whether there are applicable State requirements. As such, all patients will receive information about their breast anatomy, and this rulemaking will require consistent baseline information be provided. But the statute does not authorize FDA to categorically assert preemption over all State reporting requirements. As discussed in Response 139, Congress specifically preserved State laws that are at least as stringent as Federal law. Depending upon the circumstances, some State laws could be found to be preempted, such as less stringent State laws that make it impossible to comply with both Federal and State requirements, or that stand as an obstacle to the accomplishment of Federal goals. FDA has not performed a State by State analysis to determine whether any specific, current State law may be subject to preemption. FDA notes that no comment proffered a State law that was asserted to be subject to preemption.

We also disagree with the recommendation that FDA does not require Federal breast density report language and allow certain State breast density language to be used alone instead. Although FDA recognizes that many States have their own breast density reporting requirements, the Agency believes that consistent national breast density reporting requirements are critical in order to ensure that: (1) breast density reporting occurs in all States and (2) patients and healthcare providers receive accurate, complete, and understandable breast density information.

First, the Agency believes it is important to ensure that patients receive a baseline set of key breast density information. Not all States currently have a breast density reporting requirement. If FDA does not require breast density reporting, in those States that also do not have reporting requirements, patients and their healthcare providers generally would not receive any breast density information, which raises significant public health concerns for all of the reasons set forth in this preamble, and the preamble to the proposed rule.

Second, even in those States that already have a breast density reporting requirement, FDA believes there is value in having a single, consistent set of FDA-required information shared with the public. FDA breast density notification language is drafted by FDA subject-matter experts, contains the information FDA believes is critical to communicate, and is drafted using easily understandable language. FDA does not have the resources to monitor all State laws, particularly as they change over time, in order to ensure that the key information is being communicated consistently and effectively to patients and providers under State law. Requiring uniform breast density reporting on a Federal level ensures that patients and providers nationwide receive the appropriate information and avoids mistakes and gaps in critical information being communicated to patients and their healthcare providers.

Regarding the comment that patients may be confused by receiving Federal and State notifications and the recommendation that FDA should take measures to avoid such confusion, we note that in this final rule we have simplified the notification statements to patients with either non-dense or dense tissue, using concise and understandable language, and have concluded both statements with the recommendation, ''Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation'' (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that the clear language and the recommendation to talk directly to the healthcare provider will minimize the likelihood of patient confusion.

Regarding the potential burden on facilities, we believe the breast density notification requirement established in this final rule is simple for mammography facilities and Agency personnel to understand and implement. Ultimately, FDA anticipates that it will be easier for both facilities and the Agency if FDA requires uniform notification language, which consists of specific language for the overall assessment of breast density in the mammography report (see § 900.12(c)(1)(vi)) and four to five lines of text in the lay summary to patients (see § 900.12(c)(2)(iii) and (iv)), as opposed to permitting State language to be used alone in certain circumstances. FDA is concerned that alternative approaches, such as requiring that specific information rather than specific statements be communicated to patients, would be complex, inefficient, and difficult to administer, and would consume unnecessary resources in the long term. Moreover, including FDA-required text in mammography reports and lay summaries will not be unduly burdensome for facilities, including because facilities will not need to expend resources in crafting their own language. Rather, facilities will have to add the FDA-required text.

(Comment 141) Several comments note that it may be difficult for States and facilities to determine if State requirements are ''more stringent'' than Federal requirements, and request that FDA provide input to help determine what requirements are ''more stringent'' than the Federal requirements.

(Response 141) As explained in Response 140, all facilities providing mammography services will be required to comply with FDA's reporting requirements, regardless of whether there are applicable State requirements. As discussed in Responses 139 and 140, FDA has not conducted a State-by-State preemption analysis or evaluated whether current State laws are more or less stringent than FDA breast density

reporting requirements. We note that FDA has defined ''[m]ore stringent,'' albeit in regard to language used in section 521 of the FD&C Act (21 U.S.C. 360k), as ''a requirement of greater restrictiveness or one that is expected to afford those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act'' (21 CFR 808.3(c)).

Y. Effective Date of This Rule

(Comment 142) A comment recommends that all provisions of the rule except the density notification should become effective 6 months after publication. Conversely, some comments assert that 18 months is an inadequate period of time for facilities to implement the new requirements under the rule. A separate comment recommends that FDA consult with equipment manufacturers regarding an appropriate implementation date.

(Response 142) FDA disagrees with these recommendations. FDA does not anticipate that facilities would be able to implement all of the requirements of this rule into facility practice within 6 months without undue hardship. Based on FDA's experience with the effective date of the previous MQSA final rule (62 FR 55852), FDA concludes that 18 months is a practical timeframe for this final rule to take effect (see also Response 20). Regarding the recommendation to consult with equipment manufacturers, FDA notes that, beyond meeting any applicable FDA premarket authorization requirements for medical devices, the provisions of this final rule do not necessitate the design or manufacture of any new equipment by manufacturers. Moreover, all members of the public, including equipment manufacturers, had an opportunity to comment on the proposed rule. As such, recognizing that FD&C Act requirements have been, and continue to be, applicable to medical devices generally, notwithstanding the provisions in this final rule, FDA does not believe that specific consultation is warranted.

(Comment 143) Several comments recommend that the breast density notification requirements become effective earlier than 18 months after publication of the final rule, including specific recommendations for alternative timeframes of 30 days or 12 months. Another comment recommends allowing flexibility in the effective date of the breast density notification requirements due to the cost of making these changes.

(Response 143) FDA disagrees with these comments. FDA notes that breast density notification is an important addition to the final regulations; however, we also note that facilities should be allowed adequate time to implement these requirements into their facility practice before the requirements become effective. In addition, the breast density notification requirements should not be subject to a separate scheduled effective date than other requirements in this final rule. Facilities are not precluded from including the required breast density notifications prior to 18 months if they choose to do so, and considering any applicable State requirements. Because of the importance of establishing a consistent national standard for density reporting and notification, FDA does not agree that a longer effective date of this provision is warranted. Although there may be financial considerations for a facility in transitioning to compliance with the breast density notification requirements, FDA has concluded that 18 months is an adequate amount of time to make any necessary changes.

Z. Miscellaneous Comments

(Comment 144) A comment recommends that FDA and the ACR focus on increasing the consistency and quality of MQSA inspections by inspectors.

(Response 144) The ACR and other accreditation bodies are only involved in facility accreditation, not certification or inspection. Inspection is part of the process of certification, not accreditation. FDA trains all MQSA inspectors, both FDA employees and those who are State employees that perform MQSA inspections under State contracts with the Agency. FDA sends updated information to all inspectors whenever necessary. Furthermore, other FDA staff including Radiological Health representatives and auditors oversee and provide inspectional guidance to inspectors. The Agency concludes that these existing measures already promote consistency and quality in the MQSA inspection process.

(Comment 145) A comment recommends that FDA become the sole AB, and hire some of the staff currently employed by the ACR AB.

(Response 145) FDA disagrees with this comment. The MQSA and the implementing regulations distinguish between the separate responsibilities of the ABs and the certification agencies, which include FDA and the SCAs (see 42 U.S.C. 263b(e) and (q); part 900, subparts A and C). The ACR is one of several FDA-approved ABs. FDA (or an SCA) certifies facilities, after they have satisfied all necessary prerequisites, including accreditation by an AB.

(Comment 146) A comment recommends that FDA analyze how to improve the quality of care for women through using technology to improve the quality of mammograms and the accuracy of interpretation, and recommends that random samples of mammograms from all facilities be sent to FDA radiologists for review.

(Response 146) FDA disagrees with this comment. The ABs already initially and continually assess mammographic image quality at facilities they accredit, and are required to inform FDA of equipment or practices that may pose a serious risk to human health (see § 900.4(a)). At this time, FDA believes that the regulations afford FDA adequate opportunities to investigate any such occurrences and take action as necessary (see part 900, subpart B). The AB's responsibilities include not only reviews of the initial and renewal accreditation images, but also random image reviews of a sample of facilities accredited by the AB. The interpretation of a mammogram is a decision made by IPs, but we note that many of the MQSA regulatory requirements, including the initial and continuing qualifications for IPs and the annual medical outcomes audit, promote quality mammography practice by IPs.

(Comment 147) A comment recommends that an independent commission review the relationship between the ACR and FDA for conflict of interest.

(Response 147) FDA disagrees with this comment. The relationship between FDA and each of the ABs, including the ACR, is regulated by the MQSA and the implementing regulations and meets all applicable Federal ethics requirements (see, *e.g.,* 18 U.S.C. 201, *et seq.*).

(Comment 148) A comment asserts that improving mammography outcomes, such as lower rates of recalls and biopsies, could justify different clinical protocols, such as a younger screening age and shorter screening interval than are currently supported by the USPSTF.

(Response 148) This comment is beyond the scope of this rulemaking. This final rule requires that each facility include recall rate and certain other metrics in the audit of its mammography medical outcomes (see § 900.12(f)(1)(i) through (iii) in this final rule), but the MQSA quality standards do not specify benchmark or target values for these metrics. This rule requires that facilities compile this information and review it internally, to encourage their own quality improvement. However, decisions on which clinical practice guidelines, if any, to follow for such things as the

recommended age range or time interval for breast cancer screening with mammography are more appropriately for the healthcare provider to make.

(Comment 149) A comment recommends that FDA propose special amendments to address ''cystic fibroid breast disease,'' because the commenter states that with this condition, her mammograms are more painful and are limited by the associated breast tissue density.

(Response 149) The commenter is likely describing fibrocystic change, one of many conditions that may contribute to dense breast tissue. FDA disagrees with the recommendation to propose unique amendments to address a specific clinical condition apart from the requirements at §§ 900.12(c)(1)(vi)(A) through (D) and 900.12(c)(2)(iii) and (iv) in this final rule, which, as discussed in other responses throughout this final rule, are necessary to address the limitations of mammography in the presence of dense breast tissue caused by any etiology.

(Comment 150) One commenter cites a news article that discusses a research study showing that breast cancer screening increases the detection of early-stage cancers rather than late-stage cancers.

(Response 150) The intent of the MQSA is to ensure that the practice of mammography, across the country and whenever it is recommended by clinicians, meets consistent baseline quality standards. Decisions about whether to follow any recommendations or guidelines regarding patient age or interval for screening mammography are decisions more appropriate for the patient's clinical healthcare provider to make.

(Comment 151) One comment states only ''Should be standard of care for all women.''

(Response 151) The subject of the comment is not clear. FDA notes that the MQSA requirements apply consistently to all facilities that provide mammography services. Thus, every person who undergoes mammography at a certified facility in the United States can be assured that baseline national quality standards apply. However, decisions on whether to follow clinical practice guidelines, including recommendations for screening mammography at a certain age and/or a certain time interval, and any other clinical standards of care, are more appropriately made in the course of clinical decision-making by the provider and the patient.

(Comment 152) A comment recommends that image quality must be held to the highest possible standard.

(Response 152) FDA believes the amended regulations will continue to ensure appropriate national standards for quality mammography services. We note that provisions of the MQSA and its implementing regulations, including many that are not amended in this final rule, already address image quality. These include: the role of the ABs in clinical image review and phantom image review (§ 900.4), the eight image quality attributes that must be included in AB clinical image reviews (§ 900.4(c)(2)(i) through (viii)), personnel qualifications (§ 900.12(a)), equipment requirements (§ 900.12(b)), quality assurance requirements (§ 900.12(d) through (f)), and the general requirement that clinical images must continue to comply with the image quality standards of the facility's AB (§ 900.12(i)). We further note that some of these requirements related to the facility's responsibility to maintain clinical image quality were highlighted by the introduction in 2017 of FDA's Enhancing Quality Using the Inspection Program (EQUIP) initiative (Ref. 52).

(Comment 153) A comment recommends that FDA should spend $2.5 million per year for 10 years for public service announcements, advertisements, and a website.

(Response 153) FDA disagrees with the comment. General patient outreach and education is not within the scope of this final rulemaking. The MQSA program certifies mammography facilities and is funded largely by the user fees paid by those certified facilities. However, we note that the MQSA program maintains a public website (Ref. 65), and also occasionally uses email and social media to disseminate important information about the MQSA program. FDA also notes that the HHS Office of Women's Health, and the FDA Office of Women's Health are each committed to advancing issues regarding women's health and to providing health education materials through outreach activities and collaborative partnerships. Among other things, these offices use resources to maintain the programs and publish resources regarding cancer, mammography, and other relevant health issues.

(Comment 154) A comment recommends that FDA should grant $500,000 per year for 10 years to DenseBreast-Info for webinars and its website.

(Response 154) FDA disagrees with the comment. As noted in Response 153, general patient education and outreach are not within the scope of this rulemaking. Similarly, individual grant-making activities are also outside the scope of this rulemaking.

(Comment 155) A comment recommends that FDA name this rule in memory of an advocate for breast density notification.

(Response 155) FDA appreciates the comment. We acknowledge the important work done by advocates for breast density notification in educating the public about the significance of breast tissue density. However, we disagree with the recommendation to name this rule after any one individual. The title of the rule is based on the specific regulations being amended, but the rule is not ''named.''

(Comment 156) A comment asserts that the ''FDA device pathway'' is very different from, and much slower than, the Center for Drug Evaluation and Research Fast Track program for drug approval.

(Response 156) FDA acknowledges the comment, but notes that the pathways for premarket review of medical devices as they relate to those of drugs are outside the scope of this rulemaking. The MQSA is found under the Public Health Service Act in Title 42 of the U.S.C., and it is implemented by DMQS in FDA's CDRH. The authority for FDA's regulation of drugs and medical devices is found under the FD&C Act in Title 21 of the CFR.

VI. Effective Date and Compliance Date

This rule is effective 18 months after the date of publication in the **Federal Register**. Mammography facilities will need to be in compliance with the amended MQSA regulations in this final rule by September 10, 2024.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant

impact of a rule on small entities. Because many facilities that will be affected by this rule are defined as small businesses, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary and Accounting Statement

The final rule will modernize mammography regulations by incorporating current science and mammography best practices to improve the delivery of mammography services. These updates include requirements on recordkeeping, reporting, and communication of results. This final rule also addresses procedural requirements in several areas related to quality control and management of mammography facilities.

The benefits and costs associated with this final rule are summarized in table 1. The quantified benefits are derived from reduced mortality and breast cancer treatment costs resulting from the breast density reporting requirements. We use two methods of measuring the value of reduced mortality: the value per statistical life (VSL) approach and an approach based on the value of lost life years (LY). Under the VSL approach, the estimate of annualized benefits over 10 years ranges from $42.00 million to $232.69 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $48.42 million to $266.09 million. Under the LY approach, the estimate of annualized benefits over 10 years ranges from $12.99 million to $66.90 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $8.50 million to $37.96 million. Because there is uncertainty in the literature about the most appropriate method for analyzing reduced mortality for the population affected by this final rule, we do not present a primary value and use estimates from both methods to create the range of values in table 1. The high estimate in table 1 is based on the VSL approach, which yields the higher-bound estimate of the two methods. The low estimate is based on the LY approach, which yields the lower-bound estimate of the two methods. Other benefits that we are not able to quantify include reduced cancer morbidity and improvements in the accuracy of mammography by improving quality control and strengthening the medical audit.

The costs of the final rule include costs to mammography facilities to comply with the requirements of the regulation and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years range from $28.87 million to $45.42 million at a 7 percent discount rate with a primary value of $36.31 million. Using a 3 percent discount rate, the annualized costs range from $27.61 million to $44.16 million with a primary value of $35.05 million.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN MILLIONS 2020 DOLLARS OVER A 10-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized Monetized $/year	.....	$12.99	$232.69	2020	7	10	
		8.50	266.09	2020	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
					3		
Qualitative	Improvements in the accuracy of mammography and better management of mammography facilities.			.....	.....	.....	
Costs:							
Annualized Monetized $/year	36.31	28.87	45.42	2020	7	10	
	35.05	27.61	44.16	2020	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
					3		
Qualitative	.....	.....	.....	.....	.....	.....	
Transfers:							
Federal Annualized Monetized $/year	.....	.....	.....	.....	7	.....	
					3		
From/To	From:			To:			
Other Annualized Monetized $/year	.....	.....	.....	.....	7	.....	
					3		
From/To	From:			To:			

Effects:

State, Local or Tribal Government:

Small Business: Annual cost per affected small entity estimated as $416–$727, which would represent a maximum of 1.2 percent of annual receipts.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN MILLIONS 2020 DOLLARS OVER A 10-YEAR TIME HORIZON—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Wages:							
Growth:							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 63) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Mammography Facilities, Standards, and Lay Summaries for Patients; OMB Control Number 0910–0309.

Description: FDA is amending its mammography reporting requirements to require that the mammography report provided to the healthcare provider and the lay summary provided to the patient include basic mammography facility identification information and information concerning patient breast density. This action is intended to facilitate communication among mammography facilities, healthcare providers, and patients; facilitate the retrieval of mammography images; and help ensure that healthcare providers and patients obtain the necessary information from the mammography facility to enable a patient and their healthcare provider to make informed healthcare decisions. FDA also is including categories be added to the list of assessments that facilities are required to use in the mammography report. In addition, FDA is amending its requirements related to the transfer and provision of mammography records, the transfer and provision of personnel records upon request or facility closure, and FDA notification and mammographic records access upon facility closure.

Description of Respondents: Respondents to this information collection are facilities that perform mammographic examinations and State certification agencies. As of July, 1, 2022, FDA internal data on facilities showed that there were 8,781 facilities certified to perform mammography (Ref. 65).

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs	Total operating and maintenance costs
Mammography medical outcomes audit—900.12(f)	8,781	1	8,781	16	140,496	$2,496,452	$5,807,650

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs	Total operating and maintenance costs
Provision of personnel records to IPs—900.12(a)(4).	615	1	615	0.08 (5 minutes)	49		$55,682
Transfer of personnel records by closing facilities—900.12(a)(4).	88	1	88	5	440		
New assessment categories and breast density reporting in mammography report (one-time burden)—900.12(c)(1)(iv) to (vi).	8,781	1	8,781	23	201,963	$37,166,396	
Breast density reporting in lay summary (one-time burden)—900.12(c)(2).	8,781	1	8,781	11	96,591	6,844,077	
Transfer/provision of copies of mammograms and records upon patient's request—900.12(c)(4)(ii) and (iii).	8,781	1,135	9,966,435	0.08 (5 minutes)	797,315		
Facility closure; notification and records access—900.12(c)(4)(v).	88	1	88	32	2,816		55,682

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs	Total operating and maintenance costs
Patient notification of significant risk (by State certification agency)—900.12(j)(2).	5	1	5	100	500		
Total					1,099,674	44,010,473	111,364

[1] Numbers have been rounded.

Personnel records—§ 900.12(a)(4): Under § 900.12(a)(4), facilities are required to maintain records of training and experience regarding personnel who work or have worked at the facility as IPs, radiologic technologists, or medical physicists. Facilities must maintain records of personnel no longer employed by the facility for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months.

Also, under § 900.12(a)(4), facilities shall provide copies of personnel records to current or former interpreting personnel (physician, radiological technologist and medical physicist) upon their request. We estimate that there are, on average, seven interpreting personnel per facility (approximately 61,467 total). We estimate that 1 percent of these personnel (615 personnel annually) will request the records and that it will take approximately 5 minutes to provide the copies for each request.

Additionally, under § 900.12(a)(4), facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.

Finally, under § 900.12(a)(4), before a facility closes or ceases to provide mammography services, it will have to make arrangements for personnel to access their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records. We estimate that annually 1 percent of the total facilities will close or cease to provide mammography services and that it will take each of the facilities approximately 5 hours to transfer the records.

Medical records and mammography reports—§ 900.12(c)(1) through (4): Section 900.12(c)(1), Contents and terminology, sets forth the requirement for facilities to prepare a written report of the results of each mammographic examination performed under its certificate. Section 900.12(c)(1) requires that the report include patient identifying information, date of examination, facility name and location, the final assessment of findings (or classification as to why no final assessment can be made), name of the IP, and recommendations to the healthcare provider.

This final rule includes two additional final assessment categories and an additional classification in the mammography report and also requires an assessment of breast density in the report (§ 900.12(c)(1)(iv) through (vi)). We estimate a one-time burden for facilities to update their existing mammography reports with these new categories. Based on the Eastern Research Group (ERG), Inc.'s report, we believe this will take 23 hours per facility (Refs. 66 and 67).

Under the final rule, if the final assessment is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility must provide the report to the healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee (§ 900.12(c)(3)(ii)) within a specified timeframe. The provision of the report to the healthcare provider was not included in the currently approved information collection burden, OMB control number 0910–0309, because it was considered usual and customary practice and was part of the standard of care prior to the implementation of the regulations (see 5 CFR 1320.3(b)(2)). Provision of the mammography report to healthcare providers continues to be part of the standard of care and remains the usual and customary business practice.

Under § 900.12(c)(2), Communication of mammography results to the patients, within 30 days of the mammographic examination, each facility shall provide each patient a summary of the mammography report written in lay terms. If the final assessment is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility shall provide the patient a summary of the mammography report within a specified timeframe (§ 900.12(c)(2)). The summary shall include the name of the patient and name, address, and telephone number of the facility. The requirements for the lay summary to include this information do not result in a change to the currently approved information collection burden for § 900.12(c)(2).

Section 900.12(c)(2) also requires facilities to provide an assessment of breast density (as described in § 900.12(c)(2)(iii) to (iv)) in the lay summary. We estimate a one-time burden for facilities to update their existing lay summaries with the breast density assessments. Based on the ERG report, we believe this will take 11 hours per facility (Refs. 65 and 66).

Also, under § 900.12(c)(2)(ii), each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated.

The requirements in § 900.12(c)(2)(iii) and (iv) to provide an explanation of the breast density assessment identified in § 900.12(c)(1)(vi) are not considered to be ''collections of information'' because the language is originally supplied by the Federal government for the purpose of disclosure to members of the public (5 CFR 1320.3(c)(2)).

Under § 900.12(c)(4)(i), facilities that perform mammograms must maintain mammographic records. The rule requires that facilities implement policies and procedures to minimize the possibility of record loss and requires that records be maintained in the modality in which they were produced.

Under § 900.12(c)(4)(ii), facilities shall, upon request by or on behalf of the patient, transfer or release the mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly. Under § 900.12(c)(4)(ii) and (iii), facilities must transfer original mammograms (and copies of associated reports) or provide copies of mammograms (and copies of associated reports) within a specified period of time. Copies of mammograms must be in the same modality in which they

were produced. Moreover, for digital mammograms or digital breast tomosynthesis, the facility must be able to provide the recipient with original digital images electronically if the examination is being transferred for final interpretation. We estimate that approximately one third of patients will request transfer or release of the records and it will take approximately 5 minutes per request. To calculate the estimated number of requests, we use the estimated number of screening mammograms (29,890,141) (Ref. 62) divided by 3. This results in approximately 9,963,380 requests, or an average of 1,135 requests per facility.

Under § 900.12(c)(4)(v), before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records. Additionally, the facility must notify its accreditation body and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients. If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of § 900.12(c)(4)(i) through (iv), it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient. We estimate that 1 percent of facilities per year will close and that it will take each facility approximately 32 hours to provide notification and access to the records.

Quality assurance-mammography medical outcomes audit—§ 900.12(f): Section 900.12(f)(1) requires each facility to establish a system to collect and review outcome data for all mammographic examinations performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the IP's mammography report. The rule clarifies that positive predictive value, cancer detection rate, and recall rate must be collected during this audit.

Additional mammography review and patient and referring provider notification—§ 900.12(j): Under § 900.12(j)(1), if FDA or the State certification agency believes that mammographic quality at a facility has been compromised and may present a significant risk to human health, the facility must provide clinical images and other relevant information for review by the accreditation body or the State certification agency.

Under § 900.12(j)(2), when FDA has determined that the quality of mammography performed by the facility poses a significant risk to human health, a facility may be required to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians or healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and other relevant information. Also under the rule, State certification agencies (along with FDA) may notify patients and their providers if a facility is unable or unwilling to do so.

We received several comments related to the proposed rule. Descriptions of the comments and our responses are provided in section V of this final rule, Comments to the Proposed Rule and FDA's Response. Comments and responses related to the provisions that underlie the information collection are described in the following sections: V.A, regarding general comments; V.D, regarding retention and release of personnel records; V.E, regarding digital accessories; V.F, regarding facility identification information in mammography report and lay summary; V.G, regarding final and incomplete assessments and lay summaries; V.H, regarding deadlines for mammography reports; V.I, regarding breast density notification—general support for density notification; V.J, regarding breast density notification language; V.K, regarding breast density notification and the role of the referring healthcare provider; V.L, regarding format for image interpretation, retention, transfer, and release of copies; V.M, regarding deadlines for image transfer and the release of copies; V.N, regarding facility closure and mammography record retention; V.O, regarding mammography medical outcomes audit; V.P, regarding patient and referring provider notification; V.Q, regarding revocation of certification; V.X, regarding federalism and the relationship between Federal and State breast density reporting requirements; and V.Y, regarding timeframe for implementation of this rule. We have not made changes to the estimated burden as a result of the comments.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

X. Federalism

The MQSA established minimum national quality standards for mammography. The MQSA replaced a patchwork of Federal, State, and private standards with uniform Federal standards designed to ensure that all patients nationwide receive adequate quality mammography services. FDA has worked very closely with State officials in developing the national standards for the MQSA program and has sought and obtained input from States at every step of the process.

FDA issued final rules implementing the MQSA on October 28, 1997 (''Quality Mammography Standards,'' 62 FR 55852) and February 6, 2002 (''State Certification of Mammography Facilities,'' 67 FR 5446). As required by Executive Order 13132 (August 4, 1999), FDA prepared a federalism assessment in this latter final rule and determined that the rule was consistent with the federalism principles expressed in Executive Order 13132 (Ref. 64).

This final rule amends, among other things, the requirements in the MQSA for reporting to healthcare providers and patients to ensure that patients receive all necessary information after their mammograms, including an assessment of breast density, while not unduly burdening the mammography facility.

Although certain provisions impact Federal-State relations, FDA does not believe that they impose any additional, significant burden on the States. The division of responsibilities between FDA, the States, and State agencies will not change as the regulations will continue to provide for necessary uniformity of minimum national standards and, at the same time, provide maximum flexibility to states administering the States as Certifier program within their State, and State agencies serving as accreditation bodies.

On November 4, 2011, FDA convened a public meeting of the NMQAAC where possible amendments to the MQSA regulations, including breast density reporting, were discussed (Ref. 33). This meeting was open to the public, and time was allotted for public statements on issues of concern in the mammography field. FDA has also met and held teleconferences several times a year with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern.

The Agency also has long enjoyed a good relationship with the Conference of Radiation Control Program Directors,

Inc. (CRCPD), which is the professional organization of the State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

For the reasons discussed previously, FDA believes that this final rule is consistent with the federalism principles expressed in Executive Order 13132.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

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

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List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

■ 1. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

■ 2. In § 900.2, revise paragraphs (c)(2), (k), (z), and (aa)(1) and (2), add paragraph (aa)(3), and revise paragraph (ii) to read as follows:

§ 900.2 Definitions.

* * * * *

(c) * * *

(2) Failure to send mammography reports within 30 days to the referring healthcare provider or in a timely manner to the self-referred patient; and

* * * * *

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (*e.g.,* family member or referring healthcare provider).

* * * * *

(z) *Mammographic modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography, full field digital mammography, and digital breast tomosynthesis.

(aa) * * *

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures;

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter; or

(3) Computed tomography of the breast.

* * * * *

(ii) *Patient* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a healthcare provider or is self-referred.

* * * * *

■ 3. In § 900.4 revise paragraphs (a)(6) and (f)(1)(ii)(B) to read as follows:

§ 900.4 Standards for accreditation bodies.

(a) * * *

(6)(i) When an accreditation body denies accreditation to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body for the facility to contest the decision.

(ii) If a facility has failed to become accredited after three consecutive attempts, no accreditation body shall accept an application for accreditation from the facility for a period of 1 year from the date of the most recent accreditation failure.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(B) Review of facility documentation to determine if appropriate mammography reports are sent to patients and providers as required;

* * * * *

■ 4. In § 900.11 revise paragraph (c)(4) to read as follows:

§ 900.11 Requirements for certification.

* * * * *

(c) * * *

(4) If a facility's certificate was revoked on the basis of an act described in 42 U.S.C. 263b(i)(1), as implemented by § 900.14(a), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

■ 5. In § 900.12:

■ a. Revise paragraph (a)(4);

■ b. Add paragraphs (b)(2)(i) and (ii);

■ c. Revise paragraph (b)(11);

■ d. Add paragraph (b)(16);

■ e. Revise paragraphs (c)(1) and (2), (c)(3)(ii), (c)(4), and (f)(1);

■ f. Add paragraph (f)(4); and

■ g. Revise paragraph (j).

The additions and revisions read as follows:

§ 900.12 Quality standards.

(a) * * *

(4) *Retention of personnel records.* Facilities shall maintain records of training and experience relevant to their qualification under MQSA for personnel who work or have worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility must be maintained for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months. The facility shall provide copies of these personnel records to current interpreting physicians, radiologic technologists, and medical physicists upon their request. Facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request. Before a facility closes or ceases to provide mammography services, it must make arrangements for access by current and former personnel to their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for no less than 24 months from the date of facility closure or cessation of mammography services.

(b) * * *

(2) * * *

(i) All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type with that intended use.

(ii) A mammography unit that is converted from one mammographic modality to another is considered a new unit at the facility under this part and must, prior to clinical use, undergo a mammography equipment evaluation demonstrating compliance with applicable requirements. The facility must also follow its accreditation body's procedures for applying for accreditation of that unit.

* * * * *

(11) *Film.* For facilities using screen-film units, the facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography. For facilities using hardcopy prints of digital images for transfer, retention, or final interpretation purposes, the facility shall use a type of film designated by the film manufacturer as appropriate for

these purposes and compatible with the printer being used.

* * * * *

(16) *Equipment—other modalities.* Systems with image receptor modalities other than screen-film shall demonstrate compliance with quality standards by successful results of quality assurance testing as specified under paragraph (e)(6) of this section.

(c) *Medical records and mammography reports*—(1) *Contents and terminology.* Each facility shall prepare a written report of the results of each mammographic examination performed under its certificate. The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed, and must not consist of digital images produced through copying or digitizing hardcopy original images. The mammography report shall include the following information:

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination, facility name, and location. At a minimum, the location shall include the city, State, ZIP code, and telephone number of the facility;

(iii) The name of the interpreting physician who interpreted the mammogram;

(iv) Overall final assessment of findings, classified in one of the following categories (the assessment statement is only the word or phrase within the quotation marks):

(A) ''Negative.'' Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed);

(B) ''Benign.'' Also a normal result, with benign findings present, but no evidence of malignancy (if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed);

(C) ''Probably Benign.'' Finding(s) has a high probability of being benign;

(D) ''Suspicious.'' Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) ''Highly Suggestive of Malignancy.'' Finding(s) has a high probability of being malignant;

(F) ''Known Biopsy-Proven Malignancy.'' Reserved for known malignancies being mammographically evaluated for definitive therapy; and

(G) ''Post-Procedure Mammogram for Marker Placement.'' Reserved for a post-procedure mammogram used to confirm the deployment and position of a breast tissue marker.

(v) In cases where no final assessment category can be assigned due to incomplete work-up, one of the following classification statements shall be assigned as an assessment and reasons why no final assessment can be made shall be stated by the interpreting physician.

(A) ''Incomplete: Need additional imaging evaluation.'' Reserved for examinations where additional imaging needs to be performed before an assessment category identified in paragraphs (c)(1)(iv)(A) through (G) of this section can be given; or

(B) ''Incomplete: Need prior mammograms for comparison.'' Reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in paragraphs (c)(1)(iv)(A) through (G) of this section can be given. If this assessment category is used, a followup report with an assessment category identified in paragraphs (c)(1)(iv)(A) through (E) of this section must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained.

(vi) Overall assessment of breast density, classified in one of the following categories:

(A) ''The breasts are almost entirely fatty.''

(B) ''There are scattered areas of fibroglandular density.''

(C) ''The breasts are heterogeneously dense, which may obscure small masses.''

(D) ''The breasts are extremely dense, which lowers the sensitivity of mammography.''

(vii) Recommendations made to the healthcare provider about what additional actions, if any, should be taken. All clinical questions raised by the referring healthcare provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) *Communication of mammography results to the patients.* Each facility shall provide each patient a summary of the mammography report written in lay terms within 30 calendar days of the mammographic examination which shall, at a minimum, include the name of the patient; the name, address, and telephone number of the facility performing the mammographic examination; and an assessment of breast density as described in paragraphs (c)(2)(iii) and (iv) of this section. If the assessment of the mammography report is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility shall provide the patient a summary of the mammography report written in lay language within 7 calendar days of the final interpretation of the mammograms.

(i) Patients who do not name a healthcare provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms. If the assessment of the mammography report is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility shall send this report to the patient within 7 calendar days of the final interpretation of the mammograms.

(ii) Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated, which shall include when such patients' mammogram assessment is either probably benign, suspicious, or highly suggestive of malignancy.

(iii) If the mammography report identifies the patient's breast density as ''The breasts are almost entirely fatty'' or ''There are scattered areas of fibroglandular density,'' the lay summary shall include the statement ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.''

(iv) If the mammography report identifies the breast density as ''The breasts are heterogeneously dense, which may obscure small masses'' or ''The breasts are extremely dense, which lowers the sensitivity of mammography,'' the lay summary shall include the statement ''Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.''

(3) * * *

(ii) If the assessment is ''Suspicious'' or ''Highly Suggestive of Malignancy,'' the facility shall provide a written report of the mammographic examination, including the items listed in paragraph (c)(1) of this section, to the referring healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee of the referring healthcare provider within

7 calendar days of the final interpretation of the mammograms.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain the original mammograms and mammography reports in a permanent medical record of the patient for the longest of the following: a period of not less than 5 years, a period of not less than 10 years if no additional mammograms of the patient are performed at the facility, or a period, if any, mandated by State or local law. Facilities shall implement policies and procedures to minimize the possibility of loss of these records. The original mammograms must be retained in retrievable form in the mammographic modality in which they were produced. They cannot be produced by copying or digitizing hardcopy originals.

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly during the time specified in paragraph (c)(4)(i) of this section. Transfer of the mammograms and mammography reports must take place within 15 calendar days of the facility receiving such request. The transferred mammograms must be in the mammographic modality in which they were produced, and cannot be produced by copying or digitizing hardcopy originals. For digital mammograms or digital breast tomosynthesis, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically;

(iii) Shall upon request by, or on behalf of, the patient, provide copies of mammograms and copies of mammogram reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly during the time specified in paragraph (c)(4)(i) of this section. Release of the copies must take place within 15 calendar days of the facility receiving such request. For digital mammograms or digital breast tomosynthesis, if the copies are being released for final interpretation purposes, the facility must be able to provide the recipient with digital images electronically;

(iv) Any fee charged to the patients for providing the services in paragraphs (c)(4)(ii) or (iii) of this section shall not exceed the documented costs associated with this service; and

(v) Before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records. This access may be provided by the permanent transfer of mammographic records to the patient or the patient's healthcare provider or the transfer of the mammographic records to a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by such other facility or entity for the remainder of the time periods specified in paragraph (c)(4)(i) of this section. If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of paragraphs (c)(4)(i) through (iv) of this section, it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient. The facility must notify its accreditation body and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients.

* * * * *

(f) * * *

(1) *General requirements.* For the purposes of these audit requirements, a mammographic examination consisting of routine views of an asymptomatic patient shall be termed a screening mammogram, while a mammographic examination consisting of individualized views of a patient with breast symptoms, physical signs of breast disease, or abnormal findings on a screening mammogram shall be termed a diagnostic mammogram. Each facility shall establish a system to collect and review outcome data for all mammographic examinations performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. In addition, for cases of breast cancer among patients imaged at the facility that subsequently become known to the facility, the facility shall promptly initiate followup on surgical and/or pathology results and review of the mammographic examinations taken prior to the diagnosis of a malignancy. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians and, at a minimum, shall consist of a determination of the following:

(i) Positive predictive value—percent of patients with positive mammograms who are diagnosed with breast cancer within 1 year of the date of the mammographic examination.

(ii) Cancer detection rate—of the patients initially examined with screening mammograms who receive an assessment of ''Incomplete: Need additional imaging evaluation,'' ''Suspicious,'' or ''Highly Suggestive of Malignancy'' on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within 1 year of the date of the initial screening mammogram, expressed arithmetically as a ratio per 1,000 patients.

(iii) Recall rate—percentage of screening mammograms given an assessment of ''Incomplete: Need additional imaging evaluation.''

* * * * *

(4) The records and data required to demonstrate compliance with the requirements in paragraphs (f)(1) through (3) of this section must be retained until the annual inspection that follows the facility's analysis of that information.

* * * * *

(j) *Additional mammography review and patient and referring provider notification.* (1) If FDA or the State certification agency believes that mammographic quality at a facility has been compromised and may present a significant risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA or the State certification agency, for review by the accreditation body or the State certification agency. This additional mammography review will help FDA or the State certification agency determine whether the facility is in compliance with this section and whether there is a need to notify affected patients, their referring physicians or other healthcare providers, and/or the public that there is a significant risk to human health.

(2) Based on the results of the additional mammography review, the facility's failure to comply with the terms of the additional mammography review, or other information, FDA or the State certification agency may determine that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in this part as to present a significant risk to human health. FDA or the State certification agency may require such a facility to notify all patients who received mammograms at the facility or those patients who are determined to be at

risk due to the quality of their mammography, and their referring physicians or other healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and such other relevant information as FDA or the State certification agency may require. Such notification shall occur within a timeframe and in a manner specified by FDA or the State certification agency. If the facility is unable or unwilling to perform such notification, FDA or the State certification agency may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

■ 6. In § 900.14 revise paragraphs (a) introductory text and (a)(3), (5), and (6) and add paragraph (a)(7) to read as follows:

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for a hearing in accordance with part 16 of this chapter, that the facility, owner, operator, or any employee of the facility:

* * * * *

(3) Has failed to comply with reasonable requests of FDA, the State certification agency, or the accreditation body for records, information, reports, or materials, including clinical images for an additional mammography review under § 900.12(j), that FDA or the State certification agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

* * * * *

(5) Has violated or aided and abetted in the violation of any provision of or regulation issued pursuant to 42 U.S.C. 263b;

(6) Has failed to comply with prior sanctions imposed by FDA or the State certification agency under 42 U.S.C. 263b(h), including a directed plan of correction or a patient and referring physician notification; or

(7) Has failed to comply with requests of current or former facility personnel for records of their training or experience relevant to their qualification under MQSA, in violation of § 900.12(a)(4).

* * * * *

■ 7. In § 900.15 revise paragraph (d)(1) to read as follows:

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

* * * * *

(d) * * *

(1) References to the Centers for Medicare and Medicaid Services in 42 CFR part 498 should be read as the Division of Mammography Quality Standards (DMQS), Center for Devices and Radiological Health, Food and Drug Administration.

* * * * *

Dated: February 27, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1120

Requirements for Tobacco Product Manufacturing Practice; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1120

[Docket No. FDA–2013–N–0227]

RIN 0910–AH91

Requirements for Tobacco Product Manufacturing Practice

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

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is proposing to establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products, to assure that the public health is protected and that tobacco products are in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the proposed rule must be submitted by September 6, 2023. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by April 10, 2023 (see section ''VI. Paperwork Reduction Act of 1995'' of this document). See section V of this document for the proposed effective date of a final rule based on this proposed rule.

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 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2013–N–0227 for ''Requirements for Tobacco Product Manufacturing Practice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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.

Submit comments on information collection issues to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Requirements for Tobacco Product Manufacturing Practice.''

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Office of Regulations, or Rear Admiral Emil Wang, Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTPRegulations@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed regulation—proposed part 1120 (21 CFR part 1120)—sets forth requirements for tobacco product manufacturing practice (TPMP) and provides a framework for manufacturers of finished or bulk tobacco products to follow that would include: (1) establishing tobacco product design and development controls to prevent or minimize certain risks; (2) ensuring that finished and bulk tobacco products are manufactured in conformance with established specifications; (3) minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products; (4) requiring investigation and identification of nonconforming products, including those that have been distributed in order to institute appropriate corrective actions, such as conducting a recall as needed; (5) requiring manufacturers to take appropriate measures to prevent contamination of tobacco products; and (6) establishing traceability to account for all components or parts, ingredients, additives, and materials, as well as each batch of finished or bulk tobacco product, to aid in investigations of nonconforming tobacco products. Therefore, this proposed regulation would establish requirements for the control of tobacco product manufacturing activities and the treatment of contaminated or otherwise nonconforming tobacco products, including the investigation, evaluation, and corrective and preventive actions (CAPA) necessary to protect the public health.

These provisions are generally similar to many existing industry practices and are drafted to provide tobacco product manufacturers with flexibility in the manner they comply with the proposed requirements while assuring the protection of public health. This proposal is intended to ensure that tobacco products conform to established specifications and to help prevent the manufacture and distribution of contaminated or otherwise nonconforming products, thereby assuring that the public health is protected and that tobacco products comply with the requirements in chapter IX of the FD&C Act.

B. Summary of the Major Provisions of the Proposed Rule

The proposed regulation is divided into 10 subparts. This proposed regulation is intended to provide a framework that requires all finished and bulk tobacco product manufacturers subject to the rule (including specification developers, contract manufacturers, and repackagers/relabelers) to establish and maintain procedures for various aspects of the manufacturing, preproduction design validation, packing, and storage processes, while allowing flexibility to establish procedures that are unique to the manufacturer's facilities and activities, and appropriate for a given tobacco product. The proposed requirements are written in general terms to allow manufacturers to establish procedures appropriate for their specific products and operations. The extent of the procedures necessary to meet the regulation requirements may vary with the size and complexity of the design and manufacturing operations. Tobacco product manufacturers who have a complex manufacturing process would likely need to establish more detailed procedures to comply with the rule, while tobacco product manufacturers who have a less complex manufacturing process may need less extensive procedures.

1. Subpart A—General Provisions

Subpart A contains two proposed sections: scope and definitions. The scope section describes the purpose of this proposed regulation and the products and activities to which it applies. This proposed regulation would apply to manufacturers (foreign and domestic) of finished and bulk tobacco products. The definitions section defines the terminology applicable to the proposed requirements laid out in this notice of proposed rulemaking (NPRM). The proposed rule would define ''tobacco product manufacturer'' to mean ''any person(s), including a repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished or bulk tobacco product for sale or distribution in the United States. The manufacture of a tobacco product includes establishing the specifications of or the requirements for a tobacco product.''

2. Subpart B—Management System Requirements

Subpart B contains three proposed sections: organization and personnel; tobacco product complaints; and CAPA. The organization and personnel section would require finished and bulk tobacco product manufacturers to establish and maintain an organizational structure; have sufficient personnel; designate personnel with appropriate responsibility, including management with executive responsibility; train personnel; and maintain certain records of these activities. The tobacco product complaints section would require finished and bulk tobacco product manufacturers to establish and maintain complaint handling procedures for the receipt, evaluation, investigation, and documentation of all complaints. The CAPA section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for implementing CAPA and to maintain records of the activities required under this subpart.

3. Subpart C—Buildings, Facilities, and Equipment

Subpart C contains four proposed sections: personnel practices; buildings, facilities, and grounds; equipment; and environmental controls. The personnel practices section would require finished and bulk tobacco product manufacturers to establish and maintain procedures related to personnel practices to reduce the risk of contamination with filth biological materials, chemical hazards, or other deleterious substances, including rocks or metal shavings. The buildings, facilities, and grounds section would require such manufacturers to ensure that buildings and facilities are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. In addition, manufacturers would be required to ensure that facility grounds are maintained in a condition to prevent contamination and to control the water used in the manufacturing process. The proposed requirements would also require such manufacturers to establish and maintain procedures for proper cleaning and sanitation and animal and pest control, and maintain records of these activities to demonstrate compliance with this proposed rule. The equipment section would provide requirements for design, construction, and maintenance of equipment as well as certain additional requirements (*e.g.,* calibration) for testing, monitoring, and measuring equipment used in the tobacco product manufacturing processes and for major

equipment and processing line identification. Lastly, the environmental controls section would require that environmental control systems be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. This subpart would also require manufacturers to maintain certain records to demonstrate compliance with this proposed rule.

4. Subpart D—Design and Development Controls

Subpart D contains two proposed sections: design and development activities and master manufacturing record (MMR). The design and development activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of tobacco products, including the control of risks associated with the product, production process, packing, and storage, as well as procedures for design verification and validation. These requirements would include developing a process for identification, analysis, and evaluation of known and reasonably foreseeable risks associated with the tobacco product and its packaging as well as taking appropriate measures to reduce or eliminate risks using recognized tools for risk management. Manufacturers would also be required to maintain records of all activities required under this section.

The proposed MMR section would require manufacturers to establish and maintain an MMR for each finished and bulk tobacco product they manufacture for distribution. The proposed section would require each MMR to include tobacco product specifications, the manufacturing methods and production process procedures, and all packaging, labeling, and labels approved for use with the product. Additionally, the proposed MMR section includes requirements for the review and approval of the MMR, including any changes after initial approval.

5. Subpart E—Process Controls

Subpart E contains nine proposed sections: purchasing controls; acceptance activities; production processes and controls; laboratory controls; production record; sampling; nonconforming tobacco product; returned tobacco product; and reprocessing and rework. The purchasing controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that purchased or otherwise received products and services related to the manufacture of a finished or bulk tobacco product are from qualified suppliers and conform to established specifications. The acceptance activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for incoming and for in-process and/or final acceptance activities, including acceptance criteria, to ensure that products meet established specifications. The production processes and controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for production processes, including process specifications and process controls, process validation, and manual methods and manufacturing material. The laboratory controls section would require finished and bulk tobacco product manufacturers to demonstrate laboratory competency to perform laboratory activities associated with the manufacture of finished and bulk tobacco products and to establish and maintain laboratory control procedures for any laboratory activities conducted under proposed part 1120. The production record section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that a production record is prepared for each batch of finished or bulk product to demonstrate conformity with the requirements established under the MMR. The sampling section would require finished and bulk tobacco product manufacturers to establish and maintain an adequate sampling plan that uses representative samples based on a valid scientific rationale for any sampling performed under proposed part 1120. The nonconforming tobacco product section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for control and disposition of nonconforming tobacco product, including specific requirements for identification and segregation, investigation, and disposition and followup. The proposed returned tobacco product section would require procedures for the control and disposition of returned tobacco product, including specific requirements for identification, segregation, evaluation, and disposition. The reprocessing and rework section would require procedures for reprocessing and reworking tobacco products, including specific requirements for evaluation of the tobacco product to determine that it is appropriate for reprocessing or rework, authorization of the reprocessing or rework, and production processes, including process controls, to ensure that reprocessed and reworked tobacco product conforms to MMR specifications. Manufacturers also would be required to maintain records of all activities required under this subpart.

6. Subpart F—Packaging and Labeling Controls

Subpart F contains four proposed sections: packaging and labeling controls; repackaging and relabeling; manufacturing code; and warning plans. The packaging and labeling controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that the correct packaging and labeling is used to prevent mixups and that all packaging and labeling is approved for use by the manufacturer and complies with all requirements of the MMR as well as other applicable requirements of the FD&C Act, the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), and the Federal Cigarette Labeling and Advertising Act (FCLAA) and their implementing regulations. The section would also require the packaging and labeling control procedures to ensure that labels are indelibly printed on or permanently affixed to finished and bulk tobacco product packages; and that the packaging, labeling, storage, and shipping cases do not contaminate or otherwise render the tobacco product adulterated or misbranded. The repackaging and relabeling requirements would require finished tobacco product manufacturers to establish and maintain procedures for repackaging and relabeling operations. The manufacturing code section would require finished and bulk tobacco product manufacturers to apply a manufacturing code that contains the manufacturing date and batch number to the packaging or label of all finished and bulk tobacco products. The warning plans section would require manufacturers of finished tobacco products that are required to comply with a warning plan for tobacco product packaging, to establish and maintain procedures for implementing the requirements of such plan. Manufacturers would also be required to maintain records of all activities required under this subpart.

7. Subpart G—Handling, Storage and Distribution

Subpart G contains two proposed sections: handling and storage and distribution. The handling and storage

section would require finished and bulk tobacco product manufactures to establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. The distribution section would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that tobacco products are distributed to the initial consignee under appropriate conditions and that only those finished and bulk tobacco products approved for release are distributed. The distribution section would also require finished and bulk tobacco product manufacturers to maintain distribution records and a list of direct accounts.

8. Subpart H—Recordkeeping and Document Controls

The recordkeeping and document control requirements section establishes certain requirements for documents and records required by this rule. This section would require that all documents and records be maintained at the manufacturing establishment or another location that is readily accessible to responsible individuals of the manufacturer and to FDA and that they be written in English or an English translation be made available upon request. Documents and records required under this section that are associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records required under this section that are not associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date they were last in effect. FDA is soliciting comment on whether the timeframe for manufacturers to retain the documents and records under this section is sufficient for FDA's inspections and compliance activities or if it should be extended for an additional 1 or 2 years after the tobacco product reaches its expiration date if one exists. They also must be made readily accessible to FDA during the retention period for inspection and photocopying or other means of reproduction. This section also would require finished and bulk tobacco product manufacturers to ensure that all records are attributable to a responsible individual, legible, contemporaneously recorded, original, and accurate and to establish and maintain procedures for the approval and distribution of documents and for making changes to documents.

9. Subpart I—Small Tobacco Product Manufacturers

Subpart I explains that small tobacco product manufacturers of finished and bulk tobacco products would not have to comply with the TPMP regulation until 4 years after the effective date of the final rule.

10. Subpart J—Exemptions and Variances

Subpart J consists of five sections, and it sets forth the proposed procedures and requirements for petitioning for an exemption or variance from a TPMP requirement. Pursuant to section 906(e)(2)(B) of the FD&C Act (21 U.S.C. 387f), this subpart also would establish that a petition for an exemption or variance may be referred to the Tobacco Products Scientific Advisory Committee (TPSAC) and describe how FDA would make a determination on a petition for an exemption or variance. Finally, pursuant to section 906(e)(2)(E) of the FD&C Act, this subpart would provide that the petitioner has an opportunity for a hearing after the issuance of an order denying or approving a petition for an exemption or variance.

C. Legal Authority

Section 906(e) of the FD&C Act (21 U.S.C. 387f) states that in applying manufacturing restrictions to tobacco, FDA shall prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice (cGMP) or hazard analysis and critical control point (HACCP) methodology as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act (21 U.S.C. 387 through 387u). The proposed requirements flow from this authority and serve these goals of protecting public health and assuring compliance with chapter IX of the FD&C Act.

The proposed rule is also being issued based upon: FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the FD&C Act.

D. Costs and Benefits

The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packing, and storage of tobacco products. The TPMP requirements described in the proposed rule are expected to ensure that tobacco product manufacturers control the design and specifications of finished and bulk tobacco products, providing a level of assurance of conformity in the production of tobacco products to established and required specifications that does not occur in the existing market for tobacco products, to prevent the adulteration and misbranding of finished and bulk tobacco products, and establish controls for traceability purposes.

Estimated quantified benefits of the proposed rule arise from the value of reduced adverse events due to nonconforming finished and bulk tobacco products and from the reduction of costs associated with reduced product recalls and market withdrawals. We estimate the mean present value of benefits annualized over ten years using a seven and three percent discount rate to be $27.2 million and $29.9 million.

There are other potential benefits associated with the proposed rule which we have not quantified. First, the proposed recordkeeping provisions would support FDA's regulatory compliance activities and help FDA implement and enforce other provisions of the FD&C Act which will likely generate government cost savings. Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in the quantified benefits. Third, the proposed rule's risk assessment, CAPA, tobacco product complaints, and related provisions will facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. Other benefits include avoided spillover costs to capital markets.[1]

[1] Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers

Continued

Initial and recurring costs from this proposed rule arise from conducting tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. We estimate the mean present value of costs annualized over ten years using a seven and three percent discount rate to be $27.0 million and $28.2 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
AAMI	Advancement of Medical Instrumentation.
ALCOA	Attributable, Legible, Contemporaneously Recorded, Original, and Accurate.
ANSI	American National Standards Institute.
ASTM	American Society for Testing and Materials.
ASQ	American Society for Quality.
CAPA	Corrective and Preventive Actions.
CDC	Centers for Disease Control and Prevention.
cGMP	Current Good Manufacturing Practice.
CoA	Certificate of Analysis.
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco.
CSTHEA	Comprehensive Smokeless Tobacco Health Education Act.
Deeming Rule	Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements.
EA	Environmental Assessment.
E. coli	*Escherichia coli*.
EIS	Environmental Impact Statement.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive Order.
FCLAA	Federal Cigarette Labeling and Advertising Act.
FCTC	Framework Convention on Tobacco Control.
FDA or Agency	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	FEDERAL REGISTER.
HACCP	Hazard Analysis and Critical Control Point.
HHS	Health and Human Services.
HVAC	Heating, Ventilation, and Cooling.
IARC	International Agency for Research on Cancer.
IEC	International Electrotechnical Commission.
ISO	International Organization for Standardization.
MITC	Manufacturer Detected Methyl Isothiocyanate.
MMR	Master Manufacturing Record.
MRTPs	Modified Risk Tobacco Products.
MRTPA	Modified Risk Tobacco Product Application.
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.
NNN	N-nitrosonornicotine.
NPRM	Notice of Proposed Rulemaking.
NTRMs	Nontobacco Related Materials.
OMB	Office of Management and Budget.
OOS	Out-Of-Specification.
SE	Substantial Equivalence.
PMTA	Premarket Tobacco Product Application.
PRA	Paperwork Reduction Act of 1995.
PRIA	Proposed Regulatory Impact Analysis.
QMS	Quality Management System.
QSR	Quality System Regulation.
RYO	Roll-Your-Own.
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act.
TPMP	Tobacco Product Manufacturing Practice.
TPSAC	Tobacco Products Scientific Advisory Committee.
TSNAs	Tobacco-Specific Nitrosamines.
UPC	Universal Product Code.
USB	Universal Serial Bus.
U.S.C	United States Code.
WHO	World Health Organization.

III. Background

A. Legal Authority

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX, which provides FDA with the authority to regulate tobacco products and imposes certain obligations on tobacco product

and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated quantified benefits do not include avoided spillover costs to capital markets.

manufacturers (including importers), distributors, and retailers.

Section 901(b) of the FD&C Act establishes FDA's immediate authority over cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco,[2] and permits FDA, by regulation, to deem additional tobacco products subject to chapter IX of the FD&C Act. In the **Federal Register** of May 10, 2016 (81 FR 28973), FDA published a final rule entitled ''Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements'' (Deeming Rule) deeming all tobacco products meeting the statutory definition of ''tobacco product,'' except accessories of deemed tobacco products, to be subject to chapter IX of the FD&C Act. FDA intends for this proposed rule to apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the FD&C Act, except finished and bulk accessories of cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco.

Section 906(e) of the FD&C Act provides that in applying manufacturing restrictions to tobacco, FDA shall prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to cGMP or HACCP methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act. The requirements in proposed part 1120, including management system requirements; buildings, facilities, and equipment requirements; design and development controls; process controls; packaging and labeling controls; handling, storage, and distribution requirements; and recordkeeping and document controls, are derived from this authority. Section 902(7) of the FD&C Act provides that a tobacco product shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) of the FD&C Act or an applicable condition prescribed by an order under section 906(e)(2) of the FD&C Act. As a result, a product will be adulterated if a manufacturer fails to comply with the requirements prescribed in this proposed regulation. Violations relating to section 906(e) of the FD&C Act are subject to regulatory action by FDA, including seizure and injunction.

In addition, section 909 of the FD&C Act authorizes FDA, by regulation, to require manufacturers and importers of tobacco products to establish and maintain records, make reports, and provide information to assure that such tobacco products are not adulterated or misbranded, and to otherwise protect public health. Section 909 thus provides additional legal authority for the proposed rule's recordkeeping, reporting, and related requirements. In addition, under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has the authority to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule will help assure that tobacco products are not adulterated or misbranded under other provisions of the FD&C Act and will assist in the efficient enforcement of those other provisions. For example, section 902 of the FD&C Act provides that a tobacco product is adulterated in several circumstances including: (1) if a tobacco product consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health; (2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. (Section 902(1)–(3) of the FD&C Act.) The proposed rule will help ensure that tobacco products are not adulterated in these ways, and that appropriate records, reports, and information will be available to enforce section 902's adulteration provisions. To similar effect, section 903 provides that a tobacco product is misbranded if, for example, its labeling is false or misleading in any particular or if the product does not bear labeling that is required by an applicable tobacco product standard established under section 907 (section 903(a)(1) and (a)(9) of the FD&C Act). The proposed rule's labeling requirements will help prevent tobacco products from being misbranded in violation of section 903.

Further, section 801(a) of the FD&C Act gives FDA authority to refuse admission of tobacco products imported or offered for import into the United States in situations where it appears such products: (1) have been manufactured, processed, or packed under insanitary conditions; (2) are forbidden or restricted in sale in the country in which they were produced or from which they were exported; or (3) are adulterated or misbranded. As noted earlier, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule will assist in the efficient enforcement of the FD&C Act's import requirements under section 801(a) by requiring manufacturers of finished and bulk tobacco products to implement certain controls over their product manufacturing, preproduction design validation, packing, and storage activities, including recordkeeping, to prevent the import of tobacco products that appear to be adulterated or misbranded.

Finally, the proposed rule will assist in the performance of FDA inspections under section 704 (21 U.S.C. 374) and 905(g) (21 U.S.C. 387e(g)) of the FD&C Act.

B. Rationale for the Proposed Regulation

While all tobacco products have inherent risks to the public health, FDA is proposing TPMP requirements to minimize or prevent product problems, as well as health issues not normally associated with use of a tobacco product. For example, these requirements would help minimize or prevent the manufacture and distribution of tobacco products contaminated with foreign substances (*e.g.,* nontobacco related materials (NTRMs) such as metal, glass, nails, pins, wood, dirt, sand, stones, rocks, fabric, cloth, and plastics) which have been found in finished tobacco products as will be discussed further below. These requirements also would help minimize or prevent the manufacture and distribution of nonconforming electronic nicotine delivery systems (ENDS) e-liquids that contain nicotine concentration levels that vary from the labeled amount and vary from one ENDS product to another within the same brand (Ref. 1, Ref. 178). As explained elsewhere in this document, this potential variability in nicotine concentration, in which an e-liquid product contains significantly higher

[2] *See* Consolidated Appropriations Act, 2022, Public Law 117–103, div. P, tit. I, subtit. A, sec. 111(b) (March 15, 2022).

levels of nicotine than what is stated on the label, could be misleading to consumers concerned about nicotine delivery levels, potentially intensifying or prolonging their addiction and potentially exposing users to increased toxins (Refs. 4 and 5). Tobacco products may introduce preventable harms not normally associated with use of tobacco products due to inadequate design or manufacturing controls; for example, defective solder joints from an ENDS cartomizer (atomizer plus replaceable fluid-filled cartridge) may cause respiratory distress due to metallic particles in the aerosol (Ref. 2). This proposed regulation would help to assure that the public health is protected from these, and other, types of hazards and that tobacco products comply with chapter IX of the FD&C Act.

FDA is proposing a TPMP regulation under section 906(e) of the FD&C Act that employs a Quality Management System (QMS) approach. QMS approaches are well established and have been required (*e.g.,* 21 CFR part 820) or utilized by FDA (*e.g.,* ''FDA Guidance for Industry—Quality Systems Approach to Pharmaceutical CGMP Regulations'') in other product categories. A QMS can protect the public health in several ways. First, a QMS can enable the manufacturer to demonstrate its ability to consistently produce products that meet applicable statutory and regulatory requirements. Second, a QMS can enable a manufacturer to establish and maintain a robust design and development process for its product and to adequately identify and control nonconforming products to prevent their distribution and related potential harm. Finally, if nonconforming products are discovered, a QMS can provide the manufacturer with a recognized framework to effectively investigate and identify the nonconforming products in order to institute appropriate corrective actions such as conducting a recall as needed. If a firm is manufacturing a tobacco product that is contaminated or inconsistent with the specifications identified in an application under which it has received marketing authorization, the tobacco product may be adulterated or misbranded pursuant to section 902 or section 903 of the FD&C Act and subject to regulatory action. Thus, the proposed regulation based on a QMS approach, if finalized, would help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act.

1. Assuring That the Public Health Is Protected

The proposed regulation would help assure that the public health is protected by, among other things, minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products. A ''nonconforming tobacco product'' is proposed to be defined as any tobacco product that: (1) does not meet a product specification as set by the MMR (see proposed § 1120.44(a)(1)); (2) has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or (3) is a contaminated tobacco product (proposed § 1120.3). Nonconforming products occur for many different reasons, including inadequate sanitation practices, design issues, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate personnel training, inadequate manufacturing methods and procedures, the introduction or presence of hazards, or improper handling or storage of the tobacco product. A tobacco product that does not conform to established specifications, has incorrect packaging, labeling, or labels, or is contaminated could increase the product's risk compared to what would normally be associated with use of the product.

Tobacco products with contaminants that could have been prevented with the implementation of this proposed TPMP rule have been identified. For example, consumer complaints of foreign metal material, including sharp metal objects, in a manufacturer's smokeless tobacco (*e.g.,* chewing) products ultimately led the manufacturer to issue a voluntary recall of certain products on January 31, 2017 (Ref. 3). In other instances, smokeless tobacco products have contained rocks or metal shavings as well as other NTRMs (*e.g.,* glass, nails, pins, wood, dirt, sand, fabric, cloth, and plastics) in finished tobacco products. These NTRMs can cause cuts or lacerations to the lips and gums or result in broken teeth. This proposed regulation includes measures that will help avoid such contamination, in addition to provisions for how manufacturers would be required to handle complaints in similar situations, as well as the subsequent investigation, evaluation, and CAPA they would need to take to address such issues.

Consumers have reported additional substances not ordinarily contained in tobacco products such as biological materials (*e.g.,* mold, mildew, hair, fingernails) and chemical hazards (*e.g.,* ammonia, cleaning agents, and kerosene). Caustic cleaning chemicals may cause vomiting, nausea, allergic reactions, dizziness, numbness, or headaches.

Even when nonconforming tobacco products are not contaminated with foreign objects or substances, they may contain higher levels of a constituent than the consumer is expecting, which can have negative health effects not normally associated with the tobacco product. For example, researchers have reported on the variability of nicotine in certain ENDS e-liquids and that the labeling of these products did not accurately reflect the actual nicotine levels. For example, there have been reports of wide variability in e-cigarette manufacturing, including nicotine concentrations in e-liquid, that were inconsistent with the information contained on the product label (Ref. 178). In one study, researchers found that actual nicotine amounts differed from label amounts by more than 20 percent in 9 out of 20 original e-cigarette cartridges tested, and in 3 out of 15 refill cartridges tested (Ref. 1). In a second study, 9 of 21 samples had nicotine levels that deviated from the labeled value by more than 10%, with inconsistencies ranging from −21 percent to +22.1 percent (Ref. 4). Nicotine delivery varies not only across brands, but also within brands (Refs. 178–180). A finished ENDS that contains a nicotine concentration higher than the established specification can be more addictive. Similarly, a cigarette that does not conform to its pH specification can affect the amount of nicotine that is delivered to the user and its rate of absorption that can increase the tobacco product's toxicity and addictiveness (Ref. 6).

Nonconforming products may also occur because of design issues, which can cause the tobacco product to be more harmful. For example, an ENDS product, as designed, may have a design feature that contributes to an increased risk of fire and/or explosion. The ENDS product, during use or foreseeable misuse, can expose consumers to increased harm if the product catches fire or explodes resulting in serious burns that would not be expected from use of the product (*e.g.,* Ref. 7).

Given the dangers associated with contaminated and otherwise nonconforming tobacco products, FDA is proposing this regulation to help assure that the public health is protected by requiring that finished and bulk tobacco product manufacturers establish and maintain certain controls to prevent the manufacture and distribution of nonconforming products

that may have an adverse effect on public health.

2. Ensuring Compliance With Chapter IX of the FD&C Act

The proposed regulation would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act pursuant to section 906(e) of the FD&C Act. In particular, by requiring controls over the manufacturing process, the proposed regulation would help assure that tobacco products are manufactured in accordance with the specifications provided in their applications authorized by FDA. Specifications generally are included in four types of applications:

- Substantial equivalence (SE) report—To request marketing authorization for a new tobacco product, manufacturers may submit a report pursuant to section 905(j) of the FD&C Act (21 U.S.C. 387e) to demonstrate that the new tobacco product has the same characteristics as a predicate tobacco product, or has different characteristics than the predicate tobacco product but the information submitted demonstrates that it is not appropriate to regulate the product under section 910 because the product does not raise different questions of public health.
- Exemption from SE—To request marketing authorization for a new tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, manufacturers may request an exemption from demonstrating SE under certain circumstances (see 21 CFR 1107.1 and section 905(j) of the FD&C Act).
- Premarket tobacco product application (PMTA)—To request marketing authorization for a new tobacco product, manufacturers may submit a PMTA, which must include, among other things, a full statement of the components, ingredients, additives, and properties of the product as well as a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of the product. This pathway requires the applicant to demonstrate that marketing the new tobacco product is appropriate for the protection of public health pursuant to section 910 of the FD&C Act.
- Modified risk tobacco product application (MRTPA)—To request that a product be sold or distributed for use to reduce harm or the risk of tobacco-related diseases associated with commercially marketed tobacco products, manufacturers may submit an MRTPA, which must include, among other things, a description of the product and the formulation of the product. Applicants must demonstrate that, among other things, the product will or is expected to benefit the health of the population as a whole.

If a firm is manufacturing a tobacco product that is inconsistent with the specifications identified in the application under which it has received marketing authorization, the tobacco product may be adulterated or misbranded pursuant to section 902 or section 903 of the FD&C Act and subject to regulatory action. Such a product could have negative effects on public health. For example, a cigarette that does not meet its specifications for ventilation such that ventilation is reduced can pose public health risk through the resulting higher delivery of harmful and potentially harmful constituents (HPHCs) including nicotine (Refs. 8–9, 106, 173, and 183). FDA believes that the proposed TPMP rule (if finalized) would help ensure that tobacco products conform to the specifications in their authorized marketing applications and do not provide a more addictive or toxic product to consumers.

Pursuant to section 910(a)(1) of the FD&C Act, tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007 (''pre-existing products''), are not considered ''new tobacco products'' and thus are not subject to the premarket requirements of the FD&C Act. These products are subject to other provisions of the FD&C Act, including proposed TPMP requirements. The proposed rule would help manufacturers ensure that pre-existing tobacco products are manufactured to their original specifications, and thus do not undergo any modification that would render them ''new'' and in violation of the requirements of chapter IX of the FD&C Act because they lack proper marketing authorization. It would also help FDA identify and determine if any changes to established specifications or manufacturing methods and procedures result in a modification that would render the tobacco product ''new.''

Manufacturers must also ensure that their tobacco products are in compliance with tobacco product standards under section 907 of the FD&C Act. Tobacco product standards may reduce the death and disease caused by tobacco use, encourage cessation, decrease initiation, or reduce the harms not normally associated with tobacco use, such as nicotine poisoning. The proposed requirements would help a finished or bulk tobacco product manufacturer to ensure that, and FDA to review whether, the tobacco products conform to applicable tobacco product standards.

In addition to helping assure that tobacco products are manufactured in accordance with the specifications provided in their marketing applications authorized by FDA and that products are manufactured in accordance with applicable product standards, the proposed TPMP rule would help tobacco product manufacturers assure compliance with other requirements in chapter IX of the FD&C Act. For example, tobacco product manufacturers must submit a listing of ingredients, additives, and harmful and potentially harmful constituents to FDA under section 904 and applicable regulations under section 915 of the FD&C Act. The proposed TPMP recordkeeping requirements, including the MMR and production record requirements, could help FDA verify that the ingredients of these products are consistent with the listing of ingredients reported to FDA under section 904(a)(1) of the FD&C Act.

Similarly, under section 905(i) of the FD&C Act, copies of all labeling, and section 910(b)(1)(F) of the FD&C Act, specimens of labeling, must be submitted by tobacco product manufacturers to FDA. This helps the Agency determine if a manufacturer has included unauthorized modified risk claims on product labels or labeling or if product labeling is false or misleading or otherwise renders the product misbranded under section 903 of the FD&C Act. The recordkeeping requirements in the proposed regulation related to packaging and labeling would help the Agency make similar assessments, as well as identify variations between the submitted labeling and actual packaging and labeling.

Finally, the proposed contamination and risk management controls would help prevent products from becoming contaminated. Finished or bulk tobacco products that contain substances such as physical, chemical, and/or biological hazards may be adulterated under sections 902(1) to (3) of the FD&C Act. The proposed requirements for facilities and controls covering the manufacture, packing, and storage of tobacco products would help minimize the occurrence of these kinds of hazards and would therefore help ensure that products are in compliance with the requirements of chapter IX of the FD&C Act.

C. Development of the Proposed Regulation

FDA's development of this proposed regulation reflects its experience in regulating tobacco products, including the inspections and facility visits of tobacco manufacturing facilities it has conducted, recommendations for good manufacturing practice requirements for ENDS submitted by tobacco product manufacturers, and public comments filed in response to these recommendations (Docket No. FDA–2013–N–0227). FDA is also drawing on its experience with cGMP and HACCP regulations for other regulated products, such as foods, medical devices, drugs, and dietary supplements.

FDA's experience with biennial inspections of tobacco products has informed this proposal. Pursuant to section 905(g) of the FD&C Act, FDA has conducted hundreds of inspections of establishments engaged in the manufacture of regulated tobacco products, including cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco since October 1, 2011. FDA believes that this experience is also relevant to establishments that manufacture deemed products, which engage in many similar activities and processes. Beginning in 2017, the Agency also began inspecting manufacturing establishments of deemed tobacco products, including ENDS products.

In August 2012, FDA issued a notice in the **Federal Register** announcing an invitation to participate in its Tobacco Product Manufacturing Facility Visits program (77 FR 48992, August 15, 2012). The purpose of the program was to provide an opportunity for tobacco product manufacturing facilities, including facilities related to laboratory testing, to invite FDA staff to visit these facilities and observe their manufacturing operations. As part of this program, FDA staff visited tobacco product manufacturers, including small tobacco product manufacturers, of cigarettes, smokeless tobacco products, and cigarette papers, as well as facilities that conduct laboratory testing services for the tobacco industry. In response to a similar notice issued in 2016 (81 FR 39053, June 15, 2016), FDA staff also visited manufacturing facilities of domestic and foreign manufacturers, including small tobacco product manufacturers, of deemed tobacco products including cigars, ENDS, and e-liquids. FDA's experiences during these visits have helped to inform this proposal.

In addition, on January 10, 2012, 13 tobacco companies and a trade association of tobacco product manufacturers submitted to FDA their recommendations for regulations on cGMP. This group of industry stakeholders included manufacturers of a variety of tobacco products including cigarettes, smokeless tobacco, and snus. On May 2, 2012, representatives of the tobacco companies met with the Agency to present an overview of the recommendations and their approach to developing them. FDA established a public docket requesting public comment on these industry recommendations (78 FR 16824, March 19, 2013). These industry GMP recommendations included proposed requirements for an extensive range of manufacturing practices including: qualification of personnel; complaints and recordkeeping; procedures for nonconforming product; contamination prevention; buildings, facilities, and equipment; MMR; acceptance activities; supplier evaluation; manufacturing records; packaging and labeling; handling and storage; and general recordkeeping and document control procedures. We received comments on the industry recommendations from a variety of stakeholders including manufacturers of cigarettes, cigars, smokeless tobacco, and snus, as well as from public health advocates.

Further, on June 7, 2017, a group of 13 tobacco companies, a trade coalition representing small tobacco product manufacturers, and a standards organization representing vaping manufacturers and retailers submitted updated supplemental industry recommendations in order to provide additional cGMP recommendations for ENDS products. The supplemental industry GMP recommendations were generally similar to industry manufacturing practices that the Agency has observed through its biennial inspections. Among the cGMP requirements that industry recommended for ENDS products were specific ENDS design process and procedures, process qualification requirements to ensure that products consistently meet specifications, procedures to validate and approve test methods, and requirements for stability testing, reserve samples, and sampling plans.

FDA established a public docket requesting comment on these updated industry recommendations for good manufacturing practice requirements for ENDS (82 FR 55613, November 22, 2017). FDA received additional comments from manufacturers of a variety of tobacco products, public health advocates, and individuals sharing their experiences with ENDS. In developing this regulation, FDA reviewed and considered the recommendations from both industry proposals, as well as the comments submitted to the public docket.

FDA is proposing many requirements similar to those included in the industry GMP recommendations, particularly in the areas of personnel; contamination prevention; requirements for buildings, facilities, and equipment; development of an MMR; purchasing controls; process controls; production records; procedures for nonconforming tobacco product; complaints; packaging and labeling; distribution; and document control procedures.

However, FDA's proposal deviates from the industry GMP recommendations in several ways. First, the proposed TPMP regulation generally includes more robust provisions for procedures and records than provisions in the industry GMP recommendations. For example, the industry recommendations do not propose requirements for design and development activities generally, returned tobacco product, and warning plans, as discussed throughout this preamble. Such provisions are critical for the efficient enforcement of the FD&C Act.

Second, FDA's proposal includes additional provisions that are necessary to assure that the public health is protected and that manufacturers' tobacco products are in compliance with chapter IX of the FD&C Act. As noted, the industry GMP recommendations do not propose requirements for returned tobacco product and warning plans (see sections IV.E and IV.F.3 for a discussion of these FDA proposals and why FDA believes they will help assure the protection of the public health). In addition, to ensure that tobacco product manufacturers can demonstrate that their tobacco products consistently conform to established specifications, an important public health objective, the proposed rule includes additional requirements for environmental controls, process validation, laboratory controls, and sampling. Moreover, this document includes proposed requirements for design and development activities, as well as complaint, CAPA, and nonconforming product investigations. To address risks not normally associated with use of tobacco products, FDA is also proposing manufacturing code and distribution record requirements to facilitate the traceability of nonconforming products and enable tobacco product manufacturers and FDA to take appropriate corrective actions to protect the public health.

FDA also has chosen not to propose certain requirements in the industry cGMP recommendations which, in some cases, would have been more burdensome than FDA's proposed requirements. For example, FDA considered industry recommendations stating that TPMP requirements should be modified for ENDS given that they are different from other tobacco products. FDA's proposed rule, instead, utilizes an ''umbrella'' approach with flexible requirements, similar to other cGMP regulations, that would apply to the wide variety of tobacco products offered for sale or distribution. For example, the scope of covered tobacco products in the 2017 supplemental industry cGMP recommendations covers manufacturers and suppliers of ENDS components and parts and included an additional requirement for stability tests to determine appropriate storage conditions and expiration dates for finished ENDS products. However, FDA believes that such requirements are unnecessary and that the FDA proposal to cover bulk tobacco product manufacturers and the proposed requirements for design and development controls, process controls, and handling and storage requirements are sufficient to address the design, manufacture, and storage of ENDS products.

Further, the industry GMP recommendations include a requirement for a HACCP analysis for ENDS and e-liquids. While the Agency considered requiring HACCP plans in this proposal, as discussed in section IV.D.1, FDA determined that use of a risk management process would be more flexible for manufacturers while still assuring that the public health was protected.

FDA also did not include the industry's proposed GMP recommendation to require reserve samples of the e-liquid-containing component/product from each lot or batch of finished ENDS products, similar to the reserve samples that are required for medical products. While reserve samples could be useful for determining a root cause for any nonconforming products or addressing any customer complaints, we believe that the proposed documentation and recordkeeping requirements are sufficient to address any investigation required under the proposed rule. For example, for a released product found to be nonconforming because of its nicotine concentration, under the proposed rule, the manufacturer and/or FDA could review the MMR and the purchasing, acceptance activities, and production records to determine the nicotine concentration of the released product as well as who conducted the testing and signed off on the release of the product. FDA's request for comments includes comments both on industry GMP recommendations that FDA is proposing in these requirements, and industry GMP recommendations that FDA is not proposing.

In addition to the industry GMP recommendation, FDA considered its existing cGMP regulations for other regulated products and evaluated them for their suitability and applicability to tobacco products. Specifically, FDA considered the medical device quality system regulation (QSR) (part 820), and the food, dietary supplement, and drug cGMP regulations (21 CFR parts 110, 111, 210, and 211, respectively). In addition, FDA examined its regulations on HACCP systems, such as preventive controls for human foods, juice HACCP regulations, and fish and fishery products HACCP regulations (21 CFR parts 117, 120, and 123, respectively).

FDA also considered voluntary industry cGMP and quality system standards in developing this proposal. For example, FDA evaluated the American E-Liquid Manufacturing Standards Association's voluntary E-Liquid Manufacturing Standards (Ref. 10). The Agency also considered the International Organization for Standardization (ISO) ISO 9001:2015—Quality management systems—Requirements (Ref. 11); ISO 31000: 2018—Risk Management—Principles and Guidelines (Ref. 12).

FDA considered the quality systems and QMS requirements in FDA's medical device QSR and pharmaceutical cGMP for the 21st century (Ref. 13) in designing the proposed rule. The Agency believes certain aspects of those regulations are informative but not wholly applicable to tobacco products because of certain key differences between tobacco products and medical products regulated by FDA. For example, marketing applications for medical products are evaluated to determine whether they are ''safe and effective.'' Unlike medical products, tobacco products cannot be ''safe and effective'' even if used as intended and, therefore, the FD&C Act requires that marketing applications for tobacco products be evaluated under different standards (see, *e.g.,* the ''appropriate for the protection of the public health'' standard under section 910 of the FD&C Act). FDA has taken these differences into account in developing the proposed rule. For example, while the Agency has included requirements for CAPA, it has decided not to propose continuous process improvement requirements as part of this rule.

The Agency's proposed rule utilizes an ''umbrella'' approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Because this regulation would apply to many different types of tobacco products, the proposal does not prescribe in detail how a manufacturer must produce a specific tobacco product. Rather, the proposed regulation provides the framework that all manufacturers would follow by requiring that manufacturers establish and maintain procedures and fill in the details that are appropriate to a given tobacco product.

V. Description of the Proposed Regulation

A. General Provisions

1. Scope

The Tobacco Control Act gave FDA immediate authority over cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco. In addition, the Tobacco Control Act gave FDA the authority to promulgate regulations deeming other tobacco products subject to its authorities in chapter IX of the FD&C Act. In the **Federal Register** of May 10, 2016, FDA issued the Deeming Rule deeming all other products meeting the statutory definition of tobacco product to be subject to FDA's regulatory authority under chapter IX of the FD&C Act, except accessories of deemed products. 81 FR 28974. That rule became effective on August 8, 2016.

As discussed in proposed § 1120.1(a), FDA is proposing TPMP requirements that would apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the FD&C Act (*e.g.,* cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, ENDS, e-liquids, pipe tobacco, cigars, hookah tobacco, nicotine gels, and dissolvable tobacco products) but not their related accessories.

FDA proposes to define a ''finished tobacco product'' as a tobacco product, including any component or part, sealed in final packaging (*e.g.,* a pack of cigarettes, a can of moist snuff). For the purposes of the ''finished tobacco product'' definition, a ''package'' is a pack, box, carton, or container of any kind or, if no other container, any wrapping, including cellophane, in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. As discussed in more detail below, the proposed

definition of finished tobacco product also includes components or parts of tobacco products sealed in final packaging (*e.g.,* rolling papers, filters, filter tubes, or e-liquids sold separately to consumers or as part of kits). FDA intends for this TPMP rule to cover manufacturers of finished tobacco products to help assure that the public health is protected and that those products are in compliance with chapter IX of the FD&C Act.

FDA proposes to define a ''bulk tobacco product'' as any tobacco product that is not sealed in final packaging but is otherwise suitable for consumer use as a tobacco product (*e.g.,* bulk cigarettes, bulk RYO tobacco, bulk pipe tobacco). As discussed in more detail below, the proposed definition of bulk tobacco product also includes components or parts of tobacco products that are not sealed in final packaging but are otherwise suitable for consumer use as tobacco products (*e.g.,* bulk filters, bulk e-liquids). Products that are suitable for consumer use as tobacco products are those products that do not require further processing by a tobacco product manufacturer, such as mixing, cutting, curing, blending, or adding components or parts, ingredients, additives and materials, before they can be used by a consumer. For example, an e-liquid not sealed in final packaging is suitable for consumer use as a tobacco product because it requires no additional processing by a tobacco product manufacturer before it can be used by a consumer in an ENDS device; it requires only final packaging and labeling to be a finished tobacco product. A product can be suitable for consumer use as a tobacco product even if it *could* undergo additional processing by a manufacturer, such as blending, as long as it does not *require* further processing by a manufacturer before use by a consumer. For example, coconut and pineapple e-liquids not sealed in final packaging would be considered bulk tobacco products because they are suitable for consumer use as tobacco products, even if they might later be blended together by a manufacturer to make piña colada e-liquid.

FDA is including bulk manufacturers within the scope of this proposed rule in order to cover critical regulatory gaps that would occur if the rule were to only cover manufacturers of finished tobacco products. Bulk manufacturers provide bulk tobacco products, such as bulk cigarettes, bulk RYO or pipe tobacco, and bulk e-liquids, to finished tobacco product manufacturers who merely package and/or label the products for consumer use. Bulk tobacco products are suitable for consumer use as tobacco products with no additional processing by a tobacco product manufacturer and, therefore, should be regulated in the same manner as finished tobacco products. If the scope of the rule were limited to finished tobacco product manufacturers, then entities that perform key manufacturing steps other than final packaging and labeling for consumer use, such as design and development, blending, mixing, cutting, processing, assembling, and compounding, might not be subject to any TPMP requirements. Inadequate controls in earlier stages of manufacturing could result in contaminated or otherwise nonconforming bulk tobacco products that would not be detected by a finished tobacco product manufacturer during packaging and labeling operations. In addition, a finished tobacco product manufacturer that packages or labels a bulk tobacco product may not be able to conduct adequate investigations of product complaints and implementing CAPA for issues related to product design or production processes.

As noted above, the proposed definitions of finished and bulk tobacco products would include finished and bulk components or parts of tobacco products. FDA proposes to define ''component or part'' for purposes of proposed part 1120 consistent with the definition of ''component or part'' in the Deeming Rule, codified at 21 CFR 1143.1. Accordingly, a component or part would mean any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics, or (2) to be used with or for the human consumption of a tobacco product; but would exclude anything that is an accessory of a tobacco product. The requirements of proposed part 1120 would apply to manufacturers of finished and bulk components or parts of tobacco products. This would include manufacturers of finished or bulk RYO tobacco, papers, and filters, ENDS e-liquids, atomizers, batteries (with or without variable voltage), and cartomizers (atomizer plus replaceable fluid-filled cartridge).

In determining whether software or an assembly of materials might be ''intended or reasonably expected'' to alter or affect a tobacco product's performance, composition, constituents, or characteristics, or to be used with or for the human consumption of a tobacco product (and, therefore, whether the software or assembly of materials is a ''component or part''), the manufacturer's subjective claims of intent are not controlling. Rather, FDA considers all relevant evidence, including direct and circumstantial objective evidence, which encompasses a variety of factors, such as circumstances surrounding the distribution of the product or the context in which it is sold, sales data, and how the product is used by consumers.

The requirements of proposed part 1120 would also apply to manufacturers of finished or bulk products for general consumer use (*i.e.,* products not specifically designed for use with tobacco products) that meet the definition of finished or bulk tobacco products (including finished or bulk components or parts). For example, the requirements of proposed part 1120 would apply to manufacturers of finished or bulk batteries who intend them to be used in an ENDS device, for example by labeling or co-packaging the batteries with an ENDS device. Similarly, the rule would apply to manufacturers of finished or bulk food grade flavors who intend the flavors to be used with e-liquids. Likewise, the rule would apply to the manufacturer of a screen sold at a hardware store for a variety of general uses if that manufacturer labels the screen for use with a tobacco product, such as an ENDS, or co-packages the screen with a tobacco product.

The proposed rule would not apply to manufacturers of accessories of finished or bulk tobacco products. FDA proposes to define an ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. This proposed definition is the same as the definition of ''accessory'' under 21 CFR 1100.3 and under 21 CFR 1143.1. Examples of accessories of finished and bulk tobacco products include ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a

tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is maintaining the combustion of the tobacco. Accessories of deemed products are not currently subject to chapter IX of the FD&C Act. At this time, FDA believes that the proposed requirements of this rule assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act without applying the requirements to manufacturers of accessories of cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, and deemed tobacco products.

2. Umbrella Approach

This proposed rule utilizes an ''umbrella'' approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Thus, the proposed regulation provides the framework that requires all finished and bulk tobacco product manufacturers subject to the rule (including specification developers, contract manufacturers, and repackagers/relabelers) to establish and maintain procedures that are unique to the manufacturer's facilities and activities, and appropriate for a given tobacco product. The proposed requirements are written in general terms to allow manufacturers to establish procedures appropriate for their specific products and operations. The extent of the procedures necessary to meet the regulation requirements may vary with the size and complexity of the design and manufacturing operations. Tobacco product manufacturers who have a complex manufacturing process would likely need to establish more detailed procedures to comply with the rule, while tobacco product manufacturers who have a less complex manufacturing process may need less extensive procedures.

3. Specification Developers

As discussed in proposed § 1120.1(a), manufacturers of finished and bulk tobacco products include specification developers, contract manufacturers, and repackagers and relabelers. If a specification developer designs and establishes tobacco product specifications of a finished or bulk tobacco product and provides the specifications to a contract manufacturer to physically manufacture the product, both the specification developer and the contract manufacturer would be engaged in the manufacture and/or preproduction design validation of finished or bulk tobacco products for purposes of this rule and would be required to comply with this proposed rule. This approach is similar to other cGMP and HACCP regulations that have been applied to other FDA-regulated products, such as part 820, QSR for medical devices, and part 211, cGMP for finished pharmaceuticals.

A specification developer is a person who controls the design and development of a tobacco product and/or initiates or creates the specifications for the product. Such activities are important steps in the manufacture and preproduction design validation of a tobacco product. A specification developer is, in concept, like an architect who creates a ''blueprint'' of a tobacco product. A specification developer may be the same party that physically manufactures the tobacco product or a separate entity that only provides specification development services to another manufacturer, who then physically manufactures the tobacco product. FDA is aware that some tobacco product manufacturers have established an organizational structure that places the specification development functions in an entity separate from the entity in charge of physically manufacturing the finished or bulk tobacco product; these entities develop and usually control changes to the specifications of the tobacco product. Such entities are specification developers under the proposed rule.

A tobacco product manufacturer may utilize a specification developer to initiate or create the specifications of a finished or bulk tobacco product when the manufacturer lacks knowledge or expertise in product design and development. Specifically, a manufacturer may want to produce a tobacco product with certain features but lack the knowledge needed to design such a product and translate the desired features into particular product specifications. For example, a cigarette manufacturer who wants to manufacture a cigarette with certain constituent yields and consumer sensory qualities may use a specification developer to create appropriate specifications for the product, such as the specific tobacco blend, paper type and grade, filter ventilation, additives, and other features. A tobacco product manufacturer who intends to manufacture a dissolvable lozenge, orb, or strip smokeless tobacco product may similarly involve a specification developer to create appropriate product specifications such as tobacco mixtures, pH, additives, colorants, size and shape, and packaging materials. A tobacco product manufacturer who wants to commercially market an e-cigarette with certain performance features such as particular power levels, aerosol particle size, pressure drop, airflow, and puff count may similarly use a specification developer who can design a product with such features and translate them into appropriate specifications, including cartridge, atomizer, heating element, battery, and circuit board/software specifications.

FDA proposes to regulate specification developers under this rule because product design and the development of product specifications are integral parts of the manufacturing and preproduction design validation process. Product design and specification development are important because these can affect the level of risk or harm (*e.g.,* toxicity, addictiveness) a tobacco product consumer may be exposed to when using tobacco products, and, in the absence of proper controls, can also result in harm not normally associated with the use of a tobacco product.

FDA has authority to include requirements about product design in its TPMP regulation. Specifically, section 906(e) of the FD&C Act provides, in part, that FDA shall prescribe regulations requiring that the methods used in and the facilities and controls used for tobacco-product manufacture and preproduction design validation (including a process to assess the performance of a tobacco product) conform to current good manufacturing practice, or HACCP methodology. Requiring specification developers to comply with TPMP provisions is consistent with that authority.

FDA believes that it is necessary to apply the proposed TPMP regulation to specification developers because of their key role in the manufacture and preproduction design validation of finished and bulk tobacco products and because, under certain circumstances, a specification developer may be the most appropriate party or even the only capable party, to adequately perform certain activities required under the proposed regulation. Design and development frequently involve knowledge of trade secrets and/or other confidential commercial information, and a specification developer may not

share such information with the entity that physically manufactures the finished or bulk tobacco product.

Such activities include, for example, conducting adequate investigations of product complaints and implementing CAPA for issues related to product design. For example, if complaints are received that users are experiencing respiratory distress from the aerosol of an ENDS product, only a specification developer may be able to conduct an adequate investigation to determine the cause of problems and implement the necessary actions to correct and prevent the problems. The finished or bulk ENDS manufacturer who physically manufactures the product may be able to rule out a manufacturing problem (*e.g.,* defectively manufactured solder joints), but it may not be able to determine the cause of the problem if the issue relates to design (*e.g.,* metallic particles that result from improper material selection for the cartomizer wires). In that case, only the specification developer may have the unique knowledge regarding the product's design and history of specification development necessary to determine the cause of the problem and how to address it.

Similarly, if complaints are received that the software of an ENDS product that controls the heat and temperature functions is being altered or hacked by users and causing malfunctions that result in overheating, fires, or explosions, the specification developer—not the manufacturer who physically manufactures the product—would have the expertise to conduct a thorough investigation and initiate a CAPA to redesign the software to prevent this user misuse.

Specification developers are also the only party capable of adequately performing certain activities included in the proposed product development control requirements, such as identifying known or reasonably foreseeable risks associated with the design of the tobacco product and/or package as well as design verification and validation activities. With product design and development knowledge, the specification developer would be in the best position to identify and take appropriate measures to treat risks associated with the design of the tobacco product and package that are not normally associated with the use of the tobacco product and package, or that it determines constitute an unacceptable level of risk. For example, a specification developer of a dissolvable tobacco product (*e.g.,* a tobacco lozenge) would have the knowledge to address possible misuse of the product by a child that could cause choking or inadvertent exposure and to take appropriate measures to redesign the size and shape of the tobacco product or redesign the packaging. As another example, a specification developer of a heat-not-burn tobacco product would have the knowledge to assess whether the product could reach temperatures that could cause burns and to take appropriate measures to reduce this risk.

Accordingly, FDA believes that requiring specification developers to comply with the proposed TPMP requirements is essential to ensure that the proposed TPMP regulation operates as intended.

4. Foreign Manufacturers

Further, FDA is proposing that foreign manufacturers of finished or bulk tobacco products that are imported or offered for import into the United States be covered under this TPMP rule. In accordance with section 906(e) of the FD&C Act, FDA believes that covering foreign manufacturers is necessary to assure the protection of the public health. The risks associated with the tobacco product, production process, packaging, and storage are the same for all tobacco products covered by this proposed rule, regardless of where they are manufactured, and all can be addressed by the same types of controls. For example, the proposed design and development controls (proposed subpart D) would address these risks, including risks associated with the design of ENDS products that are primarily designed and manufactured in China and for which there have been numerous reports of battery fires and explosions (*e.g.,* Ref. 7).

In addition, having the proposed rule apply to foreign manufacturers of finished or bulk tobacco products would be necessary to ensure that imported tobacco products comply with chapter IX of the FD&C Act. For example, the proposed controls (*e.g.,* design and development controls, MMR, acceptance activities, and production record requirements) would help to ensure that imported tobacco products meet all applicable tobacco product standards, and thus avoid being adulterated or misbranded. A tobacco product which is subject to a tobacco product standard is adulterated under section 902(5) of the FD&C Act unless the product is in all respects in conformity with the standard. Similarly, a tobacco product subject to a tobacco product standard is misbranded under section 903(a)(9) of the FD&C Act unless it bears such labeling as may be prescribed in the standard.

5. Vape Shops Engaged in the Manufacture of Tobacco Products

Vape shops are establishments that generally, among other things, sell a variety of products including ENDS, replacement pieces, hardware, custom mixed e-liquids, and other related accessories. Sales of such products, standing alone, would not constitute finished or bulk tobacco product manufacturing. However, some vape shops are also tobacco product manufacturers under the Deeming Rule, 81 FR at 29044, because they also (for example) mix or prepare e-liquids or create or modify aerosolizing apparatuses for direct sale to consumers for use in ENDS. Under the proposed regulation, vape shops engaged in these additional activities would be manufacturers of finished or bulk tobacco products. When such vape shops are engaged in the manufacture, preproduction design validation, packing, and storage of finished or bulk tobacco products within the meaning of the proposed rule, they would be subject to the requirements in this proposed TPMP rule. Requiring such manufacturers to comply with TPMP requirements, as proposed, is important for protecting the public health because products manufactured at the retail level pose many of the same public health risks as those manufactured upstream, and possibly additional risks related to the lack of standard manufacturing practices and controls. A vape shop that does not engage in the activities described above would not be a finished or bulk tobacco product manufacturer subject to the requirements of this proposed part 1120. In addition, as set out immediately below, proposed § 1120.1(b) would require a finished and bulk tobacco product manufacturer to comply only with requirements applicable to its finished and bulk tobacco product manufacturing operations. Therefore, smaller tobacco product manufacturers (such as vape shops that engage in some but not all of the activities described above) would be able to tailor their procedures to suit their smaller operations while still complying with the proposed TPMP requirements.

6. Compliance With Requirements Applicable to Operations

Proposed § 1120.1(b) clarifies that if a tobacco product manufacturer engages in some operations subject to the requirements of proposed part 1120, but not others, the manufacturer need only comply with those requirements applicable to the operations in which it is engaged. This is the same approach

used in the drug cGMP regulation at § 210.2(b) and the device QSR at § 820.1(a)(1).

For example, a manufacturer of finished e-liquids would not need to comply with the warning plan requirements in proposed § 1120.98 because e-liquids are only required to bear a single warning. Similarly, a finished cigarette manufacturer who does not engage in repackaging or relabeling operations would not need to comply with the repackaging and relabeling requirements in proposed § 1120.94. Likewise, a specification developer who only designs/creates the MMR for another manufacturer's tobacco product and does not engage in any physical manufacturing would not be subject to, for example, the proposed requirements in subparts C (Buildings, Facilities, and Equipment), E (Production Processes and Controls), and G (Handling, Storage, and Distribution). If manufacturers believe a requirement is not appropriate or necessary to ensure that the public health is protected and that the tobacco product will be in compliance with this chapter, they may petition for an exemption or variance from all or part of the regulation pursuant to proposed § 1120.142.

Proposed § 1120.1(c) clarifies the term ''where appropriate,'' which appears several times in proposed part 1120. As discussed in proposed § 1120.1(c), when a requirement is qualified with ''where appropriate,'' it is deemed to be appropriate unless the tobacco product manufacturer documents in writing (on paper or electronically) an adequate justification prior to abstaining from implementing the requirement. An adequate justification would address why abstaining from the requirement would not result in a nonconforming tobacco product or in the manufacturer not being able to carry out necessary corrective actions. In this circumstance, the manufacturer need not petition for or receive an exemption or variance under § 1120.140. Proposed § 1120.1(d) notes that requirements in proposed part 1120 are intended to protect the public health and assure that tobacco products are in compliance with the relevant provisions of the FD&C Act and explains that the failure to comply with any applicable provision in proposed part 1120 would render the tobacco product adulterated under section 902(7) of the FD&C Act.

7. Other Manufacturers and Request for Comment

At this time, FDA is not proposing to apply these proposed TPMP requirements to manufacturers of tobacco products other than finished and bulk tobacco products. In particular, the proposed regulation will not reach manufacturers of components or parts that are not offered for sale, sold, or otherwise distributed to consumers, *i.e.,* components or parts for further manufacture. For example, the rule would not apply to manufacturers of filter tow material and cigarette tipping paper that are intended or reasonably expected to be used to manufacture a cigarette, because those products are not sold to consumers. The proposed rule's current scope does not reach such components or parts directly, but rather requires incoming tobacco product components or parts, ingredients, additives, and materials to be subject to purchasing controls and acceptance activities implemented by finished and bulk tobacco product manufacturers to ensure that they meet established specifications. In addition, FDA is not currently proposing to apply these proposed requirements to manufacturers of accessories.

FDA is soliciting comment on the scope of the proposed rule, as well as whether the scope of this regulation should be expanded to reach more than finished and bulk tobacco products. If you believe that FDA should expand the scope of this proposed rule to reach additional tobacco products, please explain why you believe FDA should take that approach; which proposed requirements, if any, should apply to other manufacturers; whether the regulation should cover manufacturers of all regulated tobacco products, including all components or parts, or only manufacturers of certain products; as well as any public health data and information that would support what you believe would be the appropriate scope of this rule. Alternatively, if you believe that FDA should limit the scope of the proposed regulation, please explain why you believe the scope of the rule should be more limited than finished and bulk tobacco product manufacturers and provide any data or information that would support that such a limited scope would still assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act.

8. Definitions

Proposed § 1120.3 sets forth the meaning of terms used in proposed part 1120.

- *Accessory.* We propose to define ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is used to maintain the combustion of the tobacco.
- *Additive.* We propose to define ''additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body.
- *Batch.* We propose to define ''batch'' as a specific identified amount of tobacco product produced in a unit of time or quantity and that is intended to have the same specifications. FDA proposes to give tobacco product manufacturers flexibility to determine what unit of time or quantity is appropriate for their product, and how batches would be designated. For example, manufacturers likely would define a batch for cigarette production, which is almost continuous, differently

than a batch for smokeless tobacco, which likely would be defined based on the amount processed in a vat through the fermentation process.

• *Brand.* We propose to define ''brand'' as a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

• *Bulk tobacco product.* We proposed to define ''bulk tobacco product'' as a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product. Products that are suitable for consumer use as a tobacco product are those products that do not require further processing by a tobacco product manufacturer before they can be used by a consumer, such as mixing, cutting, curing, blending, and adding components or parts, ingredients, additives and materials. A tobacco product can be suitable for use even if it *could* undergo additional processing by a manufacturer as long as it does not *require* further processing by a manufacturer before use by a consumer. Examples of bulk tobacco products include bulk RYO tobacco, bulk pipe tobacco, bulk RYO filters, and bulk e-liquids. However, cigarette paper that is supplied on a bobbin roll would not be considered a bulk tobacco product because it would need to be cut into rolling paper sizes or combined/glued with filters to make cigarette tubes. The terms ''bulk tobacco product'' and ''finished tobacco product'' are distinguishable because bulk tobacco products are not sealed in final packaging, whereas finished tobacco products are sealed in final packaging.

• *Characteristic.* We propose to define ''characteristic'' as the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

• *Component or Part.* We propose to define ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

• *Contaminated tobacco product.* We propose to define ''contaminated tobacco product'' as a tobacco product that contains a substance not ordinarily contained in that tobacco product. ''Not ordinarily contained'' refers to a substance that is not intended or expected to be in that tobacco product. As stated in proposed § 1120.3, an example of a contaminated tobacco product is a smokeless tobacco product with metal fragments in the tobacco filler.

• *Design.* We propose to define ''design'' as the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product.

• *Direct accounts.* We propose to define ''direct accounts'' as all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

• *Establish and maintain.* We propose to define ''establish and maintain'' as to define, document in writing (on paper or electronically), implement, follow, and update. Multiple requirements in the proposed regulation direct manufacturers to ''establish and maintain'' certain procedures. For example, proposed § 1120.12(e)(1) would require tobacco product manufacturers to establish and maintain procedures for identifying training needs and establishing training frequency for personnel based on the work the employee performs. Therefore, to comply with proposed § 1120.12(e)(1), a manufacturer would be required to create written procedures for identifying and meeting training needs, implement and follow the written procedures, and update the procedures as needed.

• *Equipment.* We propose to define ''equipment'' as any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product. Equipment used during testing and laboratory activities conducted as part of the manufacturing process would be covered under this proposed definition.

• *Finished tobacco product.* We propose to define ''finished tobacco product'' as a tobacco product, including any component or part, sealed in final packaging. Additional examples of finished tobacco products include a pack of cigarettes, a can of moist snuff, and rolling papers, filters, filter tubes, or e-liquids sold to consumers. One finished tobacco product may contain others. For example, a carton of cigarette packs (which are finished tobacco products) is also a finished tobacco product, because, like a cigarette pack, a carton is a tobacco product sealed in final packaging. As noted below, final packaging means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. (See definition of packaging).

• *Ingredient.* We propose to define ''ingredient'' as tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through chemical action during tobacco product manufacturing.

For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:

—The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds;
—the reaction of sodium hydroxide with citric acid to form sodium citrate;
—the production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive;
—products of thermolytic reactions,
—such as the production of carboxylic acids from sugar esters;
—products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides; and
—products of acid-base reactions, such as removal of a proton from protonated nicotine to generate the basic form of nicotine (''free'' nicotine). 86 FR 55300 at 55313 (Oct. 5, 2021).

• *Label.* We propose to define ''label'' as a display of written, printed, or graphic matter upon the immediate container of any article. For finished tobacco products, the term label means a display of written, printed, or graphic matter upon the immediate container of any finished tobacco product. Likewise, for a bulk tobacco product, the term label means a display of written, printed, or graphic matter upon the immediate container of any bulk tobacco product.

• *Labeling.* We propose to define ''labeling'' as all labels and other

written, printed, or graphic matter: (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

• *Management with executive responsibility.* We propose to define ''management with executive responsibility'' as one or more designated personnel who have the authority and responsibility to ensure compliance with TPMP requirements, including allocating resources and making changes to the organizational structure, buildings, facilities, equipment or the manufacture, preproduction design validation, packing, and storage of a tobacco product. These employees are typically senior employees with the authority to establish or make changes to tobacco product manufacturing policies. Such person(s) also would be responsible for ensuring that TPMP requirements are communicated, understood, implemented, and followed at all levels of the organization.

• *Manual method, process, or procedure.* We propose to define ''manual method, process, or procedure'' as any nonautomated method, process, or procedure, including processes performed by hand with or without the use of equipment.

• *Manufacturing.* We propose to define ''manufacturing'' as the manufacturing, fabricating, assembling, processing, or labeling, including the repackaging or relabeling, of a tobacco product. The term ''manufacturing'' includes establishing the specifications of a finished or bulk tobacco product. Examples of manufacturing activities include expanding (a process used with the tobacco leaf, typically dry ice expanded tobacco), homogenizing, mixing, and formulating a tobacco product.

• *Manufacturing code.* We propose to define ''manufacturing code'' as any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date followed by the batch number. The purpose of the manufacturing code is to allow manufacturers and FDA to identify the production batch of a particular finished or bulk product that has been released for distribution. This information is intended to help determine the product's history (*e.g.,* batch production records) and assist manufacturers and FDA in the event of a nonconforming product investigation and any corrective actions to be taken as a result of the investigation.

• *Manufacturing date.* We propose to define ''manufacturing date'' as the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished or bulk tobacco product is packaged for distribution. The manufacturing date is included in the manufacturing code.

• *Manufacturing material.* We propose to define ''manufacturing material'' as material used in or used to facilitate the manufacturing process that is not equipment and is not intended to be part of the product. Such material would have to contact the tobacco product or tobacco product-contact surface. An example of manufacturing material would be a mold release agent used to facilitate the release of a tobacco product from a mold.

• *Master manufacturing record (MMR).* We propose to define ''master manufacturing record'' as a document or designated compilation of documents containing the established specifications for a tobacco product including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product. Tobacco product specifications, as used in this definition, may be established by the manufacturer or required by FDA. The MMR may be prepared either as a single document (or single file of documents) or as a product-specific index system that references and includes the location of all the required information.

• *Nonconforming tobacco product.* We propose to define ''nonconforming tobacco product'' as any tobacco product that does not meet a product specification in the MMR (see proposed § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or is a contaminated tobacco product.

• *Not normally associated.* We propose to define ''not normally associated'' as not an inherent risk of using the tobacco product. In this context, the inherent risk would be associated with using the specific category of tobacco product. For example, inherent risks of using cigarettes include cancers of the mouth, throat, larynx, esophagus, trachea, lung, stomach, liver, pancreas, kidney, bladder, cervix, and colon/rectum, as well as one form of leukemia (Ref. 14). Other examples of inherent risks of using cigarettes include stroke, heart disease, peripheral vascular disease, COPD, tuberculosis, asthma, pneumonia and other respiratory diseases (id.). Examples of inherent risks of cigars include oral, laryngeal, pharyngeal, and esophageal cancers, as well as lung cancer and heart disease (Ref. 15). Examples of inherent risks of smokeless tobacco include oral and pancreatic cancers (Ref. 16).

Examples of risks not normally associated with tobacco products include lacerations of the gums or lips due to metal fragments found in chewing tobacco; broken teeth caused by rocks found in chewing tobacco; bodily injury caused by an exploding battery of an ENDS product; vomiting, nausea, allergic reactions, dizziness, numbness, or headaches caused by toxic chemical compounds found in nonconforming products; a serious illness caused by a tobacco product contaminated by aflatoxin from a fungus; and acute breathing difficulties associated with an allergic reaction to a contaminated tobacco product (*e.g.,* Ref. 17).

• *Package* or *packaging.* We propose to define ''package'' or ''packaging'' as a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers (this is also referred to as final package or final packaging), or in which a bulk tobacco product is offered for sale, sold, or otherwise distributed (including commercial distribution and interplant transfers). For example, under the proposed definition, a carton offered for sale to consumers, which holds individual cigarette packages, would be considered a ''package'' or ''packaging.'' However, a shipping crate that holds multiple cartons of cigarettes, or other multiple quantities of finished tobacco products, for distribution to retailers would not be considered ''packages'' or ''packaging,'' because such shipping crates for distribution to retailers are not containers or wrapping in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. We use the terms ''package'' and ''packaging'' interchangeably throughout this proposed rule.

• *Personnel.* We propose to define ''personnel'' as all persons, including managers, staff, consultants, contractors, and third-party entities, performing services for the manufacturer subject to proposed part 1120. The term ''personnel'' includes independent contractors performing services for the manufacturer.

• *Relabeling.* We propose to define ''relabeling'' as operations in which the labeling of a finished tobacco product is subsequently changed or replaced. This may be performed by the same person who originally labeled the product. For example, if a finished tobacco product fails an acceptance activity because it bears the wrong label, the manufacturer

may relabel the product with the correct label.

• *Repackaging.* We propose to define ''repackaging'' as operations in which the packaging of a finished tobacco product is subsequently changed or replaced. This may be performed by the same person who originally packaged the product. For example, if the package of a finished tobacco product is damaged during storage, the manufacturer may repackage the finished product in a new package.

• *Representative sample.* We propose to define ''representative sample'' as a sample that consists of a number of units that are drawn based on a valid scientific rationale (such as random sampling) and intended to ensure that the sample accurately reflects the material being sampled.

• *Reprocessing.* We propose to define ''reprocessing'' as using tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product. FDA has observed that reprocessing is a routine manufacturing process. An example of reprocessing would be using tobacco recovered through a ripper short process for cigarettes (where tobacco is removed from rejected cigarettes using equipment such as feeders, shakers, and separators) to make other cigarettes. Similar reprocessing occurs for smokeless tobacco, where the tobacco is recovered from rejected finished or bulk tobacco products, for example, due to incorrect weight or defective packaging/labels, and then used to make other smokeless tobacco products.

• *Returned tobacco product.* We propose to define ''returned tobacco product'' as commercially distributed finished or bulk tobacco product returned to the tobacco product manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or member of the public. Individuals may return tobacco products to the manufacturer for a number of reasons, including improper weight or taste.

• *Rework.* We propose to define ''rework'' as action taken on a nonconforming or returned tobacco product to ensure that the product meets the specifications and other requirements in the MMR of a subsequently manufactured tobacco product before it is released for further manufacturing or distribution. For example, a smokeless tobacco product that fails an acceptance activity for pH level can be reworked by further fermentation.

• *Small tobacco product manufacturer.* We propose to define ''small tobacco product manufacturer'' as a tobacco product manufacturer that employs fewer than 350 employees. For purposes of this definition, the number of employees of a manufacturer includes those employees and personnel of each entity that controls, is controlled by, or is under common control with such manufacturer.

• *Specification.* We propose to define ''specification'' as any requirement with which a product, process, service, or other activity must conform. A tobacco product specification is a requirement established by the manufacturer (including specification developer, contract manufacturer, or repackager/relabeler), including a requirement established to ensure that the tobacco product meets any applicable product standard under section 907 of the FD&C Act. Tobacco product specifications can include physical, chemical, and biological specifications. Examples of physical specifications include length, circumference, and pressure drop for cigarettes, and cut size and weight for smokeless tobacco products. An example of a chemical specification is a pH level for smokeless tobacco products, and an example of a biological specification is a specification related to the use of a biological fermentation agent used during the manufacturing process for smokeless tobacco products. Examples of a production process specification are the upper and lower temperature and humidity limits for specified durations, as part of the fermentation process for a smokeless tobacco product. An example of a service specification is a requirement with which a pest control service must conform.

This proposed rule would require that the tobacco product specifications and acceptance criteria for those specifications be included in the MMR for each finished and bulk tobacco product. For example, if an ENDS manufacturer establishes a voltage specification for an adjustable, variable voltage product with a range of 3–6V, the MMR would have to indicate the voltage acceptance criteria that reflect the tolerance that is established around the upper and lower specifications.

• *Tobacco product.* The term ''tobacco product'' means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term ''tobacco product'' does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

• *Tobacco product-contact surface.* We propose to define ''tobacco product-contact surface'' to mean a surface that comes into contact with a tobacco product or a surface from which drainage (or other transfer) ordinarily occurs onto the tobacco product or onto surfaces that come into contact with the tobacco product during the normal course of operations. This definition would include surfaces of equipment that come into contact with the tobacco product.

• *Tobacco product manufacturer.* We propose to define the term ''tobacco product manufacturer'' as any person(s), including any repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States. Tobacco product manufacturer includes any person(s) who establishes the specifications for a tobacco product.

FDA does not propose to define ''tobacco product manufacturer'' to include third-party laboratories. A finished or bulk tobacco product manufacturer who uses a third-party laboratory is responsible for ensuring that the laboratory is qualified to provide services under proposed § 1120.62 and is competent to perform laboratory activities associated with the manufacture of a finished or bulk tobacco product under proposed § 1120.68. A finished or bulk tobacco product manufacturer who uses a third-party laboratory is also responsible for ensuring that it receives from the third-party laboratory all the documents and records (including all metadata) needed to comply with the proposed TPMP requirements, including, for example, proposed §§ 1120.68(c) and 1120.122. It is the finished or bulk tobacco product manufacturer, not the laboratory, that is required to comply with the laboratory control requirements in proposed § 1120.68.

• *Unique identifier.* We propose to define ''unique identifier'' as information, such as a code or number, that is maintained for each accepted incoming product that would enable the

tobacco product manufacturer and FDA to identify the supplier and unique shipment of the incoming product.

• *Validation.* We propose to define ''validation'' as confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled. An example of a validation activity would be the validation of the smokeless tobacco fermentation process, which would demonstrate that when key parameters (*e.g.,* temperature, pH, oven volatiles, and number of turns) are met, conforming product will be produced in that batch. The relevant parameters would be monitored to confirm that the batch was produced within the validated ranges for the fermentation process.

• *Verification.* We propose to define ''verification'' as confirmation by examination and objective evidence that specified requirements have been fulfilled. Examples of verification activities would include measuring a dimension such as the length or circumference of a cigarette or cigar to confirm it meets a specified requirement, conducting a laboratory analysis of a pH level to confirm it is within a specified range, and performing a visual comparison of a hand-rolled cigar against a standard or approved model to confirm the proper shape and dimensions of that finished cigar.

B. Management System Requirements

1. Organization and Personnel

Proposed § 1120.12 describes the proposed requirements for finished and bulk tobacco product manufacturers' organization and personnel. This section forms the foundation for manufacturers to adequately perform and comply with the proposed requirements under proposed part 1120. These proposed requirements are generally similar to the organization and personnel requirements in the industry recommendations, and similar practices that FDA has observed during establishment inspections.

Specifically, proposed § 1120.12(a) would require finished and bulk tobacco product manufacturers to establish and maintain an organizational structure that will ensure that their manufacturing operations meet the requirements of part 1120. The organizational structure should clearly delineate the parts of the organization and personnel responsible for complying with the proposed requirements. FDA has observed that it is standard industry practice to maintain an organizational structure, position descriptions, and employee training programs.

Proposed § 1120.12(b) would require finished and bulk tobacco product manufacturers to employ sufficient personnel to carry out the requirements of proposed part 1120. Personnel must have the background, education, training, and experience, or any combination thereof, needed to carry out the requirements of proposed part 1120. Each manufacturer should determine the appropriate background and necessary education for personnel to carry out these requirements. A manufacturer may determine that appropriate certifications and job-related trainings are necessary for a particular job function. For example, employees responsible for quality assurance could take classes or coursework relevant to their role auditing the production process and evaluating the final product for conformance to tobacco product specifications and other requirements established in the MMR. FDA recommends that such training be updated on a regular basis so that responsible employees are aware of current procedures and controls to ensure that they can consistently meet the requirements of proposed part 1120. Proposed § 1120.12(b) would also require manufacturers to maintain appropriate written records of the background, education, training, and experience of its personnel in the format described in proposed § 1120.12(f) and discussed in more detail below.

Proposed § 1120.12(c) would require each finished and bulk tobacco product manufacturer to designate, in writing (on paper or electronically), the appropriate responsibility and authority for all personnel who perform an activity subject to proposed part 1120. Therefore, while proposed § 1120.12(a) would require manufacturers to establish an organizational structure, this provision would require manufacturers to specifically designate the responsibilities and authority for those personnel who would be responsible for performing the activities required under proposed part 1120. This provision would help manufacturers to ensure that their tobacco products conform to their established specifications and reduce the likelihood that nonconforming products would be distributed to consumers.

Proposed § 1120.12(d) would require finished and bulk tobacco product manufacturers to designate, in writing (on paper or electronically), management with executive responsibility that has the duty, power, and responsibility to implement the proposed requirements under proposed part 1120. Management with executive responsibility refers to those individual(s) who are ultimately responsible for ensuring compliance with proposed part 1120. This responsibility would include the allocation of resources, including facilities, equipment, materials, controls, and personnel used for the manufacture, preproduction design validation, packing, and storage of a tobacco product. These employees are typically senior employees with the authority to establish or make changes to tobacco product manufacturing policies and ensure that they are effectively communicated throughout the organization. Management with executive responsibility would be required to establish and maintain required processes and procedures to ensure compliance with requirements under proposed part 1120. Such person(s) also would be required to ensure that TPMP requirements are communicated, understood, implemented, and followed at all levels of the organization. FDA believes that this proposed requirement is generally similar to existing industry practice.

Proposed § 1120.12(e) would require finished and bulk tobacco product manufacturers to establish and maintain training procedures. This provision would require that training procedures identify training needs and establish training frequency for personnel based on the work the employee performs. Under this provision, manufacturers should assess whether employees need periodic or refresher training. FDA is not proposing to prescribe the extent and frequency of training or type of training, but rather the Agency believes that manufacturers should have the flexibility to determine how to adequately train their personnel to perform their assigned responsibilities in accordance with proposed part 1120. For example, some tobacco manufacturing facilities are only open for portions of the year and staffed with seasonal personnel. In this case, a manufacturer may opt to train its personnel at the start of each new manufacturing season.

Proposed § 1120.12(e) would also require finished and bulk tobacco product manufacturers to train personnel on their assigned responsibility and on the TPMP requirements relevant to their responsibility. Under this provision, manufacturers would not be required to train personnel on all the requirements of the proposed regulation, but rather on the provisions of the regulation that are relevant to their assigned responsibility,

including their understanding of the relevant procedures and how to maintain applicable records. Training should also cover the consequences of improper performance so that personnel will be apprised of nonconformities that can result if they do not adequately perform their assigned responsibility and implement the tobacco product manufacturing requirements relevant to their responsibility.

Proposed § 1120.12(f) establishes the format for training records required by § 1120.12(b). These training records would be required to include the type and description of the training, the training date, the names of the parties performing and taking the training, and documentation supporting completion. Training records should demonstrate which personnel were trained, identify the training completed, and illustrate whether that personnel received the proper training for their job functions. Documentation supporting completion may include the results of an assessment or examination given to personnel upon completion of the training.

The Agency believes that the proposed organization and personnel requirements would assure that the public health is protected by requiring that the responsible individuals at all levels of the organization have the knowledge, experience, and training to ensure that the establishment manufactures and distributes tobacco products that conform to established specifications and are not contaminated during the manufacturing process. Deficiencies in personnel qualification and training could increase the likelihood that a company manufactures and distributes nonconforming tobacco products. For example, one company found that spotting and staining of nonconforming finished cigarettes was due to improper training, when personnel used plasticizer instead of casing in the manufacturing process (Ref. 18). In addition, if an employee responsible for analyzing samples in the lab is not properly trained on the techniques for sample preparation and extraction to measure for pH in smokeless tobacco, the results may be unreliable and could lead to products that do not conform to the established specifications for distribution. The pH can influence the availability of nicotine and increase the risk to consumers beyond those normally associated with the product (Ref. 19).

In addition, the Agency believes that the proposed personnel requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. In particular, the proposed requirements would help ensure that personnel with proper background and expertise are participating in and monitoring the production process, thus ensuring that the tobacco product does not become adulterated or misbranded under section 902 or section 903 of the FD&C Act. The proposed requirements also would help ensure that new and modified risk tobacco products (MRTPs) are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. For example, for an SE product, qualified personnel are needed to ensure that tobacco products are manufactured to the specifications described in the SE report. Similarly, these proposed personnel requirements would help ensure that tobacco products that were commercially marketed in the United States as of February 15, 2007 (pre-existing products), continue to be manufactured consistently with their original characteristics.

Qualified and trained personnel are vital to a controlled production process. Requiring manufacturers to have qualified personnel with designated roles and who are appropriately trained would help ensure that personnel are competent in their assigned roles. This, in turn, would help ensure that manufacturing operations are performed correctly and would reduce the chances of adulteration during the manufacturing process. For example, qualified personnel with specific responsibilities to clean tobacco product-contact surfaces would help decrease the likelihood that products contain filthy, putrid, or decomposed substances, or are otherwise contaminated by added poisonous or deleterious substances that may render the product injurious to health. This would also help ensure that products are not prepared or held under insanitary conditions.

2. Tobacco Product Complaints

Proposed § 1120.14 sets forth the requirements for the receipt, evaluation, investigation, and documentation of all complaints. FDA considers a ''complaint,'' in this context, to be any communication (including written, electronic, and oral communication) that the tobacco product does not meet expectations, is unsatisfactory or unacceptable, or appears to be a nonconforming product. Tobacco product complaints may come from any source, including healthcare professionals, consumers, the public, and businesses (*e.g.,* retailers, other tobacco product manufacturers).

The proposed requirements are generally similar to complaint handling processes that FDA has observed during establishment inspections. For example, FDA is aware that tobacco product manufacturers generally maintain complaint records containing information about nonconforming tobacco products, such as incorrectly packaged tobacco products, filters that fall off the filter rod of a cigarette, broken or torn cigarettes, filter plug problems, and irregular and improper burning of cigarettes. FDA is also aware of complaint records containing information about contaminants and hazards in finished tobacco products such as NTRMs (*e.g.,* metal, glass, nails, pins, wood, dirt, sand, stones, rocks, fabric, cloth, plastics), biological materials (*e.g.,* mold, mildew, hair, fingernails), oil or greasy spots on cigarettes, chemicals (*e.g.,* ammonia, cleaning agents, kerosene), and the presence or infestation of tobacco beetles or insects. Further, FDA is aware that manufacturers maintain reports of complaints such as exploding e-cigarettes, excessive heating during use and charging of ENDS, as well as cuts and lacerations, broken teeth, vomiting, nausea, burns, allergic reactions, dizziness, numbness, headaches, and other personal or property damage reported to tobacco product manufacturers. These experiences and records have informed the proposed complaint requirements.

Given the clear importance of tobacco product complaints in alerting manufacturers and FDA to product problems, proposed § 1120.14(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all tobacco product complaints. FDA believes it is necessary for manufacturers to establish and maintain procedures to address all activities related to complaints (*i.e.,* receipt and processing; evaluation, investigation, and documentation) in order to ensure that manufacturers properly handle complaints.

Proposed § 1120.14(a)(1) through (3) would require that the tobacco product complaint procedures ensure that each complaint is: (1) processed upon receipt in a uniform and timely manner; (2) evaluated and, if necessary, investigated, in accordance with § 1120.14(b) and (c); and (3) documented in accordance with § 1120.14(e). All complaints would need to be processed upon receipt by the

manufacturer. Even complaints that may not appear to be directly related to illness or injury (such as failure to meet a specification, defective packaging, mixup of products, product bearing wrong labeling/warning, or incorrect quantity of product) may be important in identifying a nonconforming product or other manufacturing issue. Such complaints may indicate that the product is adulterated or misbranded and that a corrective action, such as a recall, is needed. Moreover, even a complaint regarding a side effect that appears to be normally associated with tobacco use may indicate a nonconforming product or a product design issue and, therefore, would be required to be investigated. For example, a complaint about respiratory distress could be determined to be attributed to a nonconforming product due to defective solder joints from an ENDS cartomizer that results in metallic particles in the aerosol (Ref. 2). Similarly, a complaint about dizziness or nausea could be due to the addition of too many ammonia compounds and other substances to reconstituted tobacco in a cigarette, which can affect free nicotine levels.

FDA is aware that some manufacturers have a corporate complaint department that handles complaints for all establishments and others have different complaint handling units for different product types and different establishments, which could result in multiple processes for handling complaints. Therefore, under proposed § 1120.14, manufacturers should designate in their procedures which individual(s) are responsible for coordinating and performing all complaint handling functions to ensure consistent handling, categorization, and evaluation/investigation of complaints across the corporation and establishments.

Proposed § 1120.14(b) elaborates on the evaluation requirement found in proposed § 1120.14(a)(2). Proposed § 1120.14(b) would require that personnel evaluate each complaint to determine whether it could be related to: (1) a nonconforming tobacco product; (2) a product design issue; or (3) any adverse experience that is required to be reported under a regulation issued under section 909(a) of the FD&C Act or implementing regulations.[3]

Complaint information may need to be incorporated into the risk management process in proposed § 1120.42 to inform the manufacturer's risk assessment and risk treatment. For example, a manufacturer that previously determined in its risk assessment that a dissolvable tobacco product is unlikely to cause a safety hazard to users would be required to reassess its risks, pursuant to proposed § 1120.42(a)(1)(iii), if it receives complaints alleging choking adverse experiences that could change the previous risk assessment.

Proposed § 1120.14(c)(1) states that if the evaluation determines that the complaint could be related to the circumstances identified in proposed § 1120.14(b)(1) through (3), an investigation must be performed (unless it is subject to the exception as provided in proposed § 1120.14(d). For example, if a complaint evaluation indicates that an ENDS product explosion could be related to an issue with the product's design, the tobacco product manufacturer would be required to perform an investigation under § 1120.14(c). Records of previously received complaints may be relevant to this evaluation. The evaluation phase would not be required to include an analysis regarding the veracity of the complaint.

Accordingly, this proposed section would require that all complaints be processed and evaluated. However, only certain complaints would need to be investigated (*i.e.,* complaints that could be related to a nonconforming product, a product design issue, or reportable adverse experience). For example, a complaint regarding the price of the product or the size offerings distributed by the manufacturer (for example, customer complaints that the manufacturer should offer a larger package size) would need to be processed and evaluated but would not need to be investigated under the proposed rule. However, complaints regarding an exploding battery, metal or rocks found in the tobacco, or nicotine poisoning of the user (or nonuser) would need to be investigated.

As stated in proposed § 1120.14(c)(2), the complaint investigation would be required to identify the scope and cause of the issue and the risk of illness or injury it poses. If a manufacturer's investigation shows that the scope and cause of the issue cannot be determined without the involvement of another entity, such as a specification developer, contract manufacturer, or other entity or establishment that performs a manufacturing operation for the product, then the manufacturer should work together with the other entity to determine the scope and cause of the issue. This would include the timely reporting to other entities of all relevant information related to the complaint.

For example, if complaints are reported to a contract manufacturer and, after investigation, are determined to pertain to a possible product design issue, the contract manufacturer should report these complaints to the specification developer for further investigation. The specification developer has the specific knowledge of the design and development information of the finished tobacco product and would be required to conduct an investigation of the product complaints and implement CAPA, as needed pursuant to proposed § 1120.16, including potential redesign of the product. The contract manufacturer, in turn, should continue to work with the specification developer to ensure that the complaint is resolved in accordance with the proposed requirements in this section. Similarly, if a finished tobacco product manufacturer that only packages or labels bulk tobacco products receives complaints of nonconforming products that may be related to the design or manufacture of the incoming bulk tobacco product, it should report these complaints to the bulk manufacturer who must then also conduct an investigation into the scope and cause of the issue, the risk of illness or injury posed by the issue, and whether any followup action is necessary, and implement CAPA, as needed pursuant to proposed § 1120.16. The finished tobacco product manufacturer should follow up with the bulk manufacturer as needed to ensure that the product complaints have been resolved in accordance with these proposed requirements. This would include the finished tobacco product manufacturer documenting the evaluation, investigation, and any associated followup action regarding the complaint, including any information provided by the bulk manufacturer.

A complaint investigation also must determine whether any followup action is necessary, including whether a CAPA is necessary under proposed § 1120.16. Followup action could include, for example, updating a procedure, requiring refresher training, making a manufacturing process change, or other action to correct and prevent a nonconforming product or design problem; initiating a recall; reporting an adverse experience under a section 909(a) regulation; or beginning to monitor the issue to see if there is a trend that might require further action. This proposed requirement is necessary to ensure that finished and bulk tobacco product manufacturers adequately

[3] We note that, currently, there are no adverse events required to be reported under section 909(a) of the FD&C Act; however, this provision would trigger automatically should FDA issue a regulation based on section 909(a).

investigate complaints that could relate to nonconforming tobacco products, issues related to product design, and reportable adverse experiences to protect consumers, correct the issue, and prevent the same or similar problems from occurring in the future.

A complaint investigation may lead the tobacco product manufacturer to initiate a corrective action, such as a recall or a change to the manufacturing process. For example, in one case, FDA received a consumer complaint that an ENDS product created thick and searing smoke that caused an unexpected health problem, specifically, sore, raw, and swollen throat that persisted for several days (Ref. 20). If, during the investigation, the manufacturer determined that the user's health problem was due to excess voltage causing the atomizer coil to burn, these proposed requirements would ensure that manufacturers investigate the scope of such an issue, the risk of illness or injury it poses, and whether any followup action, such as a CAPA, is necessary. A tobacco product manufacturer may initiate a CAPA under proposed § 1120.16, to implement a design change to control the maximum voltage output to prevent coil overheating. While some tobacco product manufacturers may initiate such actions on their own, FDA believes that these requirements are needed to ensure that all manufacturers take these steps to assure the public health is protected.

Complaints could also identify a reasonably foreseeable risk not previously known to the manufacturer, including risks that may occur with normal use and reasonably foreseeable misuse of the tobacco product, which could relate to a design issue. FDA acknowledges that a manufacturer cannot possibly foresee every single potential misuse during the design of a tobacco product, but should the manufacturer become aware through a complaint of information about risks posed by the product due to misuse, the corrective and preventive action requirements under proposed § 1120.16 and the risk management requirements under proposed § 1120.42 would be triggered, which would include reassessing and treating the risk pursuant to proposed § 1120.42(a)(1)(iii). For example, an ENDS manufacturer may receive complaints of respiratory distress for an ENDS product and determine in its investigation that users are modifying the heating element to increase voltage in order to produce greater clouds of vapor, resulting in higher aerosol temperatures than designed that generate harmful constituents such as formaldehyde, acetaldehyde, and acrolein (Ref. 21). Knowing that information, the manufacturer would reassess and treat the risk and initiate appropriate corrective action, which may include implementing design changes to prevent a user from disassembling and modifying the heating element.

When conducting investigations, tobacco product manufacturers should also review available records related to the complaint (*e.g.,* acceptance records, nonconforming product records, or CAPA records). For example, a tobacco product manufacturer may receive complaints about an ENDS overheating. Even if the product is not returned, the manufacturer may review other complaint files and determine that complaints related to other ENDS models have been received. An investigation and review of acceptance records (see proposed § 1120.64) may reveal an increase in the number of heating element components being rejected from a particular supplier. As a result of the investigation, the tobacco product manufacturer may initiate a CAPA to increase monitoring of the supplier and require additional testing to ensure that received components meet established specifications.

Proposed § 1120.14(d) provides an exception to the requirement to conduct an investigation under § 1120.14(c). This paragraph would provide that a tobacco product manufacturer is not required to complete an investigation if it has already conducted an investigation of a similar complaint and the tobacco product manufacturer determines and documents that the previous investigation results apply and another investigation is not necessary. FDA interprets a similar complaint to be one related to the same type of nonconformity or issue and likely to have the same cause or source. Therefore, a tobacco product manufacturer would not need to conduct an investigation if its documentation includes a reference to a previous investigation and a statement explaining why the complaints were sufficiently similar such that the previous investigation results apply and another investigation is not necessary. This analysis would be based on the particular facts and circumstances at issue. For example, a tobacco product manufacturer may determine and document that it need not investigate a complaint of an ENDS overheating, because it had previously investigated a complaint and found that a particular component caused the overheating and the production record shows that the product at issue used the same component from the same supplier, before the problem was corrected.

Proposed § 1120.14(e) would require a manufacturer of finished or bulk tobacco products to maintain complaint records containing the information required by § 1120.14(e)(1) through (14). Complaints requiring investigation that may result in a risk of illness, injury, or death not normally associated with tobacco product use must be clearly identified or separated. Additional discussion of the meaning of ''not normally associated'' can be found in section II.A.2. This proposed requirement would enable tobacco product manufacturers to recognize these types of complaints and prioritize appropriate followup action.

Proposed § 1120.14(e)(1) through (14) states that the complaint record must include the following information, if available: the name of the product, including brand and sub-brand; a description of the product; manufacturing code; date the complaint was received; format of complaint (*i.e.,* oral or written); name, address, and phone number of complainant; nature and details of the complaint, including how the product was used; identification of individual(s) receiving complaint; record of evaluation by the manufacturer, including the name of the individual(s) performing the evaluation; if no investigation is undertaken, the name of the individual(s) responsible for that decision and the rationale for the decision; investigation date(s); record of investigational activities performed and personnel who performed the activities; results of investigation; and any follow up action taken, including any reply to the complainant or any corrective and preventive action taken. Some of this information would be obtained during the evaluation stage while other information would be obtained during the investigation stage, if an investigation is required. The complaint record would also include activities performed by other entities that assist in the investigation. For example, if a manufacturer reports a complaint to another entity, such as a specification developer, or contract manufacturer, because the manufacturer's investigation shows that the scope and cause of the issue cannot be determined without the involvement the other entity, then the manufacturer should include in the complaint record information regarding the investigation performed by the other entity, if available.

The information in proposed § 1120.14(e) is basic information that is

essential to any complaint investigation and necessary to ensure a thorough complaint investigation and facilitate an appropriate followup. The manufacturer should make a reasonable effort to obtain the information listed in proposed § 1120.14(e)(1) through (14). For example, should some of the basic information in proposed § 1120.14(e)(1) through (14) be missing with respect to a particular complaint, a single unsuccessful attempt to reach the complainant would not be considered by FDA to be a reasonable effort to obtain information related to the complaint. If the information described in proposed § 1120.14(e)(1) through (14) cannot be obtained, this provision would require the manufacturer to document the attempts to obtain this information and explain why the information was not included, as described in proposed § 1120.14(f).

FDA believes that these proposed requirements would assure that the public health is protected by requiring tobacco product manufacturers to systematically handle the receipt, evaluation, investigation, and documentation of all complaints to determine if there is a problem with the tobacco product, a related tobacco product, or the manufacturing process, and take appropriate action. If a tobacco product manufacturer does not have a written complaint procedure, the manufacturer may not properly evaluate and if necessary, investigate the received complaint and may fail to identify a nonconforming tobacco product, a product design issue, or a reportable adverse experience. For example, if a customer reports to a manufacturer that there are metal objects in a can of smokeless tobacco (*e.g.,* Ref. 3), and the complaint procedures do not describe how to perform an investigation, the manufacturer may not conduct an adequate investigation and take an appropriate followup action, including a corrective and preventive action that would prevent consumer illness or injury from such contaminants.

Complaints from users and nonusers are an invaluable source of information for tobacco product manufacturers. The evaluation and investigation of complaints can help a tobacco product manufacturer identify problems with a tobacco product's design, established specifications, or production process. For example, if a manufacturer is receiving complaints alleging explosions of ENDS, this proposed rule would require the manufacturer to investigate the scope and cause of the issue to determine if, for example, it is due to a design problem or manufacturing problem. The investigation may determine that the problem is due to use of a non-Original Equipment Manufacturer battery charger that does not meet the manufacturer's established specification. The U.S. Fire Administration has found that nearly 25 percent of e-cigarette fires occurred when the battery was being charged (Ref. 22). Many e-cigarettes are charged using an ordinary universal serial bus (USB) port charging connection that allows users to connect the e-cigarette to power adapters that are not provided by the original manufacturer of the device. Because the voltage and current provided by USB ports can vary significantly between manufacturers, use of a USB port or power adapter not supplied by the original manufacturer may subject the battery to a higher current than is safe, leading to thermal runaway that results in an explosion and/or fire. As a result of this complaint information, the manufacturer may initiate a CAPA pursuant to proposed § 1120.16 (and further discussed in section IV.B.3) to redesign the battery to have a proprietary connection that could only be connected to a charging unit designed to be compatible or redesign the battery management system to detect an incompatible power adapter and prevent the battery from charging. New information on increased likelihood of occurrence or severity of harm obtained from tobacco product complaints should be incorporated into the manufacturer's ongoing risk management activities (*i.e.,* review of new information that could change the original risk assessment and risk treatment) under proposed § 1120.42.

In addition, FDA believes that the proposed tobacco product complaint requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Consumer complaints about adverse experiences or product problems may indicate nonconforming tobacco products that are not being manufactured to established specifications. Therefore, these proposed complaint requirements would help tobacco product manufacturers to ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. For example, if numerous complaints are received about a product, the manufacturer may investigate and learn that the product does not have the same characteristics it had as of the pre-existing date.

Complaints can also indicate that distributed tobacco products are adulterated or misbranded under section 902 or 903 of the FD&C Act. For example, complaints could indicate that products have been ''prepared, packed, or held under insanitary conditions'' (section 902(2) of the FD&C Act). In addition, as noted previously, complaints can uncover cross-contamination in a production process that resulted in an adverse experience to the user, necessitating a change in the manufacturing process to prevent the further production of cross-contaminated products. The proposed requirements in this rule that would require manufacturers to process, evaluate, investigate, and document complaints would help them to address and prevent recurrence of such adulteration.

These proposed complaint requirements also may help ensure that the packaging, labeling, or labels of finished and bulk tobacco products comply with applicable statutory and regulatory requirements. For example, a complaint may note that tobacco products are missing labels with required warning statements causing the products to be misbranded under section 903 of the FD&C Act. The investigation may determine that adequate acceptance activities are not being performed during the packaging and labeling operations. This provision would enable the manufacturer to ensure that required warning statements are applied to prevent misbranded products from being commercially marketed.

3. Corrective and Preventive Actions

Proposed § 1120.16 sets forth the requirements for CAPA. CAPA, for purposes of proposed § 1120.16, is a systematic assessment of nonconforming tobacco products and design problems to determine the cause and implement appropriate changes to the product specifications, relevant manufacturing methods and production process procedures, and/or packaging, labeling, and labels to correct and prevent the cause of the nonconformity or design problem. CAPA also helps prevent the distribution of identified nonconforming product and helps identify design problems. These proposed requirements are generally similar to the industry recommendations and to practices of tobacco product manufacturing establishments that follow ISO 9001–2015 (Ref. 11). Tobacco product manufacturers have utilized CAPA in

the past to take appropriate actions to correct and prevent identified causes of nonconformities and design problems (*e.g.,* Refs. 23–27). FDA believes that all tobacco product manufacturers should implement CAPA procedures.

Proposed § 1120.16(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for implementing CAPAs. Specifically, proposed § 1120.16(a)(1) would require such manufacturers to review and analyze processes, process control records, complaints, production records, returned products, reprocessed products, reworked products, and other sources of data to identify existing and potential causes of nonconforming tobacco product and design problems. These sources would help manufacturers identify possible causes of nonconformities and design problems and may also help manufacturers identify previously undetected problems.

Under the proposed rule, FDA expects that manufacturers would periodically examine manufacturing processes to look for causes of nonconforming tobacco products or design problems, and take steps to prevent their occurrence. For example, under proposed § 1120.16(a)(1) (and the proposed production processes and controls provision discussed further below (see § 1120.66)), a finished or bulk e-liquid manufacturer would periodically review the mixing process for an e-liquid to determine if it has been trending towards the upper control limit for the nicotine concentration. Such an issue would require a corrective action to maintain the mixing operation within the control limits so as not to produce nonconforming product. Further, records associated with other tobacco products manufactured using the same equipment or production process, including records of tobacco complaints, acceptance activities, nonconforming product, and returned products could help determine if a repeated nonconformity is associated with a manufacturing method or procedure.

Appropriate statistical methodology must be employed where necessary to detect recurring problems. Statistical techniques (*e.g.,* Ref. 28) are useful to identify trends of nonconforming product or processes and records that indicate systemic problems that contribute to nonconformities. Appropriate statistical tools, such as trend analysis, can be used to review tobacco product complaints, process controls, nonconforming product, acceptance activities, and production records. It may be necessary to employ statistical techniques such as trend analysis to identify recurring problems across multiple batches and identify potential causes of nonconforming product or design problems, which is an important part of preventive action.

Proposed § 1120.16(a)(2) would require finished and bulk tobacco product manufacturers to investigate the cause of design problems or nonconformities relating to the tobacco product or the manufacturing process. For example, if a validated cigarette-making process has a normal 2 percent rejection rate and that rate rises to 10 percent, this provision (along with proposed § 1120.74(b)) would require the manufacturer to perform an investigation into the nonconformance of the process. In this example, we would expect the investigation to include an assessment of production batches manufactured before and after the suspect batch, including records of monitoring of the process control parameters required by proposed § 1120.66(a)(2) and continued process verification results required by proposed § 1120.66(b)(3) to determine if other batches have been affected and whether there are process deviations that require revalidation of the manufacturing process pursuant to proposed § 1120.66(a)(3).

If a manufacturer's investigation shows that the cause of the design problem or nonconformity cannot be determined without the involvement of another entity, such as a specification developer, contract manufacturer, or other entity that performs a manufacturing operation for the product, then the manufacturer should work together with the other entity to determine the cause of the design problem or nonconformity. This would include the timely reporting to other entities of all relevant information related to the design problem or nonconformity. For example, if a contract manufacturer investigates the cause of a nonconformity in accordance with proposed §§ 1120.16(a)(2) and 1120.74(b) and determines that it does not pertain to its contract manufacturing process, the contract manufacturer should report the information to the specification developer for investigation. The specification developer has knowledge of, and controls the design and development information of, the finished tobacco product and may be in the best position to investigate whether the nonconformity relates to a design problem, and to implement CAPA for issues related to product design. Similarly, if a finished tobacco product manufacturer who repackages or relabels tobacco products performs a CAPA investigation and determines that the cause of a nonconformity does not relate to its repackaging or relabeling process, it should report the nonconformity to the other manufacturer(s), who then can conduct an adequate investigation, determine the cause of the nonconformity, and implement appropriate CAPA, for example changes to process controls.

Proposed § 1120.16(a)(3) would require finished and bulk tobacco product manufacturers to identify and take actions needed to correct and prevent the recurrence of design problems and nonconformities and other related problems found in the investigation. Correction and prevention of inadequate procedures and practices should result in fewer tobacco product nonconformities. To comply with this provision, for example, a manufacturer could decide to revise and update inadequate procedures, identify and correct improper personnel training, or require refresher training on a procedure to address employees' failure to follow such procedure. When identifying such actions, manufacturers should take into account the risk of illness or injury posed by the design problem or nonconformance. The degree of corrective and preventive action taken to eliminate or minimize design problems or nonconformities should be appropriate to the magnitude of the problem and commensurate with the associated risks. For example, to address a more serious problem such as a design problem resulting in a fire or explosion, the manufacturer may need to take a more significant corrective and preventive action, such as a product redesign. When performing the CAPA in such a scenario, the manufacturer may need to incorporate its risk management process (see proposed § 1120.42(a)(1)) to assess and treat the risk.

Proposed § 1120.16(a)(4) would require finished and bulk tobacco product manufacturers to verify or validate CAPAs to ensure that the actions are effective and do not adversely affect the product. Verification, as defined in proposed § 1120.3, would refer to confirmation by examination and objective evidence that specified requirements have been fulfilled. Examples of verification activities would include measuring a dimension such as the length or circumference of a cigarette or cigar to confirm it meets a specified requirement, conducting a laboratory analysis of a pH level to confirm it is within a specified range, and performing a visual comparison of a hand-rolled cigar against a standard or

approved model to confirm the proper shape and dimensions of that finished cigar. Validation, as defined in proposed § 1120.3, would refer to confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled. An example of a validation activity would be the validation of the smokeless tobacco fermentation process, which would be used to demonstrate that when key parameters (*e.g.,* temperature, pH, oven volatiles, and number of turns) are met, conforming product will be produced in that batch. The relevant parameters would be monitored to confirm that the batch was produced within the validated ranges for the fermentation process.

Verification and validation could also include the collection and analysis of data, such as from acceptance activities and nonconforming products, to confirm that a CAPA has effectively addressed the problem. Moreover, if a tobacco product manufacturer determines that a process change is required because the existing process cannot be maintained, proposed § 1120.16(a)(4) would require the manufacturer to verify or validate that this CAPA does not adversely affect the tobacco product by, for example, modifying an established specification. Verification and validation activities provide an opportunity to demonstrate through examination and objective evidence that the proposed corrective and preventive action is effective and does not introduce new or increased risks associated with the product, production process, packing, and storage. For example, if a manufacturer receives complaints about the presence of mold in finished tobacco product, it may decide to initiate a CAPA to address this issue by changing the packaging to control the moisture content of the tobacco product. The manufacturer must verify or validate the newly redesigned packaging, for example, by confirming that the new packaging material's moisture barrier meets specified requirements or conducting shelf life testing, respectively.

Proposed § 1120.16(a)(5) would require finished and bulk tobacco product manufacturers to implement and document changes to tobacco product specifications, manufacturing methods and production process procedures, and packaging, labeling, and labels needed to correct and prevent identified causes of the design problem or the nonconformity. A tobacco product manufacturer could comply with this provision in many different ways. For example, a tobacco product manufacturer that receives consumer complaints regarding respiratory distress, may redesign an ENDS cartomizer to minimize metal and silicate particles in the aerosol (Ref. 2). Similarly, a cigarette manufacturer may determine that calibration procedures need to be revised to correct the improper application of casings applied to cut filler and prevent the recurrence of nonconforming product (Ref. 29). Another example is a manufacturer that may change solvents used on packaging (*e.g.,* benzene, toluene, methyl ethyl ketone, methyl cellosolve, cellosolve) that are found to contaminate cigarettes (Ref. 30).

Proposed § 1120.16(a)(6) would require that information related to the design problem or nonconformity and the CAPA taken be disseminated to management with executive responsibility, those responsible for acceptance activities of a tobacco product, and personnel responsible for identifying training needs in accordance with proposed § 1120.12(e). This requirement would help ensure that designated individuals who are responsible for implementing TPMP requirements are notified about design problems, nonconformities, and CAPAs and can adjust procedures accordingly.

Proposed § 1120.16(b) would require that finished and bulk tobacco product manufacturers maintain records of all activities conducted under this section and that these records include the date and time, the individual performing the activity, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. For purposes of this proposed part 1120, FDA interprets ''reconstruct,'' in this context, to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. Although FDA is not proposing to prescribe a particular format to document CAPA activities, this provision would require tobacco product manufacturers to document all of the actions taken to address the requirements under this section (*e.g.,* Refs. 24–26).

The proposed § 1120.16 requirements would help assure that the public health is protected by requiring tobacco product manufacturers to perform a systematic assessment of nonconforming products and design problems to determine and address the cause. For example, nonconforming product can result from inadequate or nonexistent tobacco product or process specifications; failures of or problems with purchasing controls; inadequate process controls; improper facilities or equipment; inadequate training; and inadequate manufacturing methods and procedures.

The proposed requirements would help ensure that nonconformities and design problems are thoroughly investigated and effective CAPA are taken to eliminate or minimize them and potential harms to the consumer. For example, under this proposed section, an ENDS manufacturer that receives complaints about respiratory distress and metallic aftertaste from use of an ENDS product may initiate a CAPA investigation. The manufacturer may determine that the cartomizer aerosol contains traces of tin, copper, nickel, and silver metals attributed to poor solder joints from the cartomizer supplier (Ref. 2), and take a CAPA to change suppliers, use different cartomizer materials, and implement solder joint reliability testing as an acceptance activity (see § 1120.64). While individual tobacco product manufacturers may have used CAPA in the past, these proposed requirements would ensure that all finished and bulk manufacturers take these actions to prevent harms that could occur as a result of design problems and nonconforming products.

CAPA can also help minimize or prevent contamination of finished or bulk tobacco product. For example, due to increased consumer complaints of plastic or Styrofoam material in finished tobacco products, a manufacturer may initiate a CAPA to implement an optical sorter to prevent the introduction of non-ferrous NTRMs into finished and bulk tobacco products.

The proposed CAPA requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by establishing procedures for the manufacturer to follow in taking appropriate action on nonconforming and contaminated tobacco products both prior to, and after the manufacturer starts, marketing the products. For example, a CAPA to prevent the introduction of non-ferrous NTRMs into finished or bulk tobacco products, as discussed above, would help ensure that the product is not adulterated under section 902(a)(1) of the FD&C Act. Moreover, these provisions would help ensure that appropriate measures are taken to address new or MRTPs that do not conform to the specifications provided by the manufacturer to FDA in the relevant tobacco product applications (*i.e.,* SE Report, SE exemption request, PMTA, MRTPA) and that pre-existing tobacco products are manufactured consistent with their original characteristics.

C. Buildings, Facilities, and Equipment

1. Personnel Practices

Proposed § 1120.32 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel of personnel. Under this proposed requirement, the procedures must include requirements to ensure that contact between the personnel and the tobacco product manufacturer or the environment would not result in contamination of the tobacco product. These proposed requirements are generally similar to personnel practices that FDA has observed during establishment inspections. Personnel can contaminate tobacco products by unintentionally transferring bacteria, viruses, or disease through the handling of tobacco products, and contamination (*e.g.,* physical or microbial) may occur at any time during the manufacturing process. Therefore, this proposed rule would require each tobacco product manufacturer to set up appropriate, consistent, and effective measures to prevent personnel from contaminating tobacco products. Examples of such measures for ''cleanliness, personal practices, and apparel'' can include outer garment requirements, personal cleanliness, restrictions on jewelry and other loose items, adequate hand washing before handling a tobacco product, use of gloves, head coverings, or other protective equipment, and daily checks on these practices.

This proposed requirement would help ensure that the public health is protected by helping to prevent tobacco products from becoming contaminated, which can adversely affect public health over and above the risk normally associated with the use of the product. The proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. These measures would prevent a likely source of contamination and nonconformity and help ensure that products are not manufactured under insanitary conditions. Therefore, the requirements would help ensure that products are not adulterated under section 902 of the FD&C Act.

2. Buildings, Facilities, and Grounds

Proposed § 1120.34(a) would require finished and bulk tobacco product manufacturers to ensure that any buildings and facilities used in or for the manufacture, packaging, or storage of a tobacco product are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. These proposed requirements are generally similar to the controls for buildings, facilities, and grounds in the industry recommendations, and to practices that FDA has observed during establishment inspections.

The construction, design, and location of the physical plant provide the infrastructure that enables a tobacco product manufacturer to conduct its manufacturing operations. Therefore, this proposed rule would require that each building and facility be maintained in an appropriate condition to prevent tobacco product contamination. The term ''suitable,'' as used in this provision, would mean that the construction, design, and location of facilities would enable proper cleaning and sanitizing, maintenance, and operation. Examples of buildings and facilities that are inadequately constructed, designed or located would include facilities that are constructed of particle board that have exposed wood chips or flakes that could become a physical hazard, facilities that are constructed of porous material and cannot be adequately cleaned and sanitized, and buildings and facilities whose equipment is so tightly placed that it prevents adequate cleaning and maintenance of the building or facility. For the buildings and facilities to facilitate ''proper operations'', they should be constructed, designed, and located in a manner to facilitate the logical flow of manufacturing activities from receipt and storage of incoming materials, processing, packaging, and warehousing. FDA is not proposing to require specific activities to satisfy this requirement; rather the proposed rule is intended to provide flexibility for manufacturers to determine what is appropriate based on the specific manufacturing activities performed at the establishment.

Proposed § 1120.34(a)(1) would require that buildings and facilities have adequate lighting. FDA would consider this requirement satisfied if lighting conditions enable the tobacco product manufacturer to perform necessary manufacturing operations, including cleaning, sanitation, and maintenance. Among other things, this requirement is necessary to identify insanitary conditions that may not be visible with inadequate lighting. For example, tobacco product manufacturers may utilize visual inspection to remove NTRMs from the production area and inadequate lighting may make it difficult for personnel to identify and remove these materials. Manufacturers should also take measures to make sure that lighting is not a source of contamination. For example, lighting should not attract pests that can contaminate or otherwise render the tobacco products adulterated or misbranded under section 902 or 903 of the FD&C Act. Manufacturers should cover lighting fixtures or use shatter-proof bulbs to prevent tobacco products from becoming contaminated with glass shards if the light bulbs shatter.

Proposed § 1120.34(a)(2) would require that buildings and facilities have adequate heating, ventilation, and cooling (HVAC). HVAC equipment and systems are used to maintain the environmental conditions of buildings and facilities. For example, a manufacturer may establish temperature, relative humidity, and air flow conditions necessary for storage, handling, or processing (such as mixing, cutting, or blending) of tobacco product. Use of fans and other air-blowing equipment can maintain air ventilation to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate product or otherwise render product adulterated. This requirement would help ensure that the HVAC equipment is designed and maintained to prevent contamination of tobacco products. For example, manufacturers should prevent conditions such as damaged or exposed HVAC duct insulation hanging over processing equipment or leakage of hydraulic fluid from an HVAC system on tobacco products that may contaminate tobacco products (*e.g.,* Ref. 31). While some tobacco product manufacturers may already take such actions to control environmental conditions, these proposed requirements would ensure that all manufacturers take these actions to prevent contamination that could occur due to an inadequate HVAC system.

Proposed § 1120.34(a)(3) would require finished and bulk tobacco product manufacturers to utilize adequate plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination or creating insanitary conditions. For example, water pipes should be designed so condensation does not fall on the tobacco product or tobacco product-contact surfaces, which can cause contamination. In addition, floors cleaned with water (or water-soluble products) should be designed with floor drains to facilitate adequate drainage. Water by-products, sewage, and waste can be a source of contamination if they touch a tobacco product-contact surface or become a part of the tobacco product. Improper control of drainage, sewage, and waste also can result in pooling and create insanitary conditions or attract

pests that may contaminate tobacco products with filth. Filthy conditions from improper control of drainage, sewage, and waste can be transferred throughout the facility on shoes and equipment.

Proposed § 1120.34(a)(4) would require that buildings and facilities have adequate waste collection, storage, and disposal. Adequate waste collection, storage, and disposal includes not creating malodors that contaminate tobacco products or result in an attraction, harborage, or breeding places for animals and pests. Trash bins should have lids and be periodically emptied to help reduce the potential for insanitary conditions from microbial contamination and pests.

Proposed § 1120.34(a)(5) would require finished and bulk tobacco product manufacturers to provide adequate readily accessible handwashing and toilet facilities. The facilities must provide for water at suitable temperatures and appropriate cleaning and sanitation materials. FDA considers adequate hand-washing and toilet facilities to have hand-cleaning and sanitizing preparation areas, towel service or suitable drying stations, water control valves, appropriate signs, shelving or hooks on which to rest garments while using the toilet, and trash bins that are properly constructed and maintained. Handwashing and sanitizing, when used with water at suitable temperatures and with appropriate cleaning and sanitation materials, are an important means of preventing tobacco product contamination by personnel.

Proposed § 1120.34(b) would require finished and bulk tobacco product manufacturers to maintain the facility grounds in a condition to prevent contamination. The grounds consist of the actual physical property where the buildings and facilities are located. Inadequately maintained grounds can, for example, present a pest harborage area that can be a source of contamination.

Proposed § 1120.34(c) would require finished and bulk tobacco product manufacturers to ensure that water used in the manufacturing process, including water that is or may become part of the tobacco product (*e.g.,* water used as an ingredient or water used on a tobacco product-contact surface) is potable, will not contaminate the tobacco product, is maintained under positive pressure (*e.g.,* to prevent back siphonage that can draw water from a contaminated source into the water supply system due to leaks or gaps in the mains, cross-connections, or valves), and is supplied from sources that comply with all applicable Federal, State, and local requirements. Water is commonly used in the manufacture of tobacco products, and water that is untreated may be contaminated with *Escherichia coli* (*E. coli*) and coliform bacteria. All piping systems, hydrants, taps, faucets, hoses, buckets, and other equipment used for the delivery of water that is used as an ingredient or for use on tobacco product-contact surfaces, should be designed, constructed, maintained, and operated in such a manner as to prevent contamination of the water.

Under this proposal, the manufacturer's water supply should come from a source for which adequate controls exist for testing, treatment, and removal of contaminants (*e.g.,* microbes and heavy metals).

Therefore, proposed § 1120.34(c) would require that the water be supplied from sources that comply with all applicable Federal, State, and local requirements. For example, state governments have water departments that administer the public water system and have specific requirements to ensure that the water is safe for consumption and use.

Proposed § 1120.34(d) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the cleaning and sanitation of buildings, facilities, and grounds, including procedures for the use of any cleaning compounds, sanitizing agents, pesticide chemicals, rodenticides, insecticides, fungicides, fumigating agents, and other toxic materials. An establishment's poor cleaning and sanitation practices can increase the likelihood of tobacco product contamination. A tobacco product manufacturer should take into account the construction, design, and location of the buildings and facilities as well as the manufacturing operations, when establishing cleaning and sanitation procedures.

Specifically, proposed § 1120.34(d)(1) would require that manufacturers' cleaning and sanitation procedures detail the cleaning schedules, equipment, and materials to be used in the cleaning and sanitization, as appropriate, of the buildings, facilities, and grounds.

Proposed § 1120.34(d)(2) would require that these procedures include measures to ensure that materials used for cleaning and sanitation are identified, held, used, and stored in a manner to protect against contamination of tobacco products and tobacco product-contact surfaces. For example, FDA has observed on inspections that cleaning and sanitation materials are sometimes stored in unmarked containers in the manufacturing area (*e.g.,* Ref. 32) and, consequently, may be inadvertently used or mixed with tobacco product ingredients, additives, or materials. This proposed provision would help prevent this potential source of contamination. To help ensure that the use of cleaning and sanitation materials are used in a manner that protects against contamination, manufacturers should ensure that such materials are appropriate for their intended purpose and nontoxic where possible.

Proposed § 1120.34(d)(3) also would require that the use of cleaning and sanitation materials comply with all applicable Federal, State, and local requirements related to their application, use, or storage. For example, hazardous cleaning and sanitation chemicals must be handled, used, and stored in a manner consistent with the information contained in their safety data sheets in accordance with the hazard communication standard at 29 CFR 1910.1200(g).

Proposed § 1120.34(e) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds to protect against contamination of tobacco products. This proposed requirement would be limited to manufacturing activities and not extend to agricultural activities including growing, cultivation, or curing of raw tobacco (21 U.S.C. 387). FDA acknowledges that tobacco is an agricultural crop and, therefore, there is the likelihood that there will be a certain level of animals and pests (such as tobacco beetles) in the tobacco. However, it is important that manufacturers take appropriate action to control these animals and pests, which can cause contamination (*e.g.,* Refs. 33–35). FDA is proposing that these procedures include requirements for establishing threshold criteria for animals and pests. This provision is intended to provide manufacturers with flexibility to quantitatively establish acceptable levels of animals or pests, such as insects, that may be present and the levels that would necessitate action to control and minimize infestation in order to avoid contamination. Manufacturers may employ pest control or fumigation to minimize the presence of animals or pests (*e.g.,* Ref. 36). This approach is recognized in the Cooperation Centre for Scientific Research Relative to Tobacco's (CORESTA's) Good Agricultural Practices Guidelines (Ref. 37).

This paragraph also would require that the procedures include a requirement that any pesticide, including rodenticides, insecticides, or fungicides used in the buildings, facilities, and grounds be registered in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) and used in accordance with its label, as applicable and used in a manner that protects against contamination. Pesticides, such as rodenticides, insecticides, or fungicides are useful to manufacturers to monitor, control, and minimize animals and pests effectively. The tobacco product manufacturer should follow all applicable pesticide labels, identify proper compounds to be used, use the correct concentration, and apply it as directed to avoid contamination (*e.g.,* Refs. 38–40). Use of inappropriate pest control chemicals or use in an inappropriate manner can contaminate tobacco products (*e.g.,* Refs. 39–41).

Proposed § 1120.34(f) would require finished and bulk tobacco product manufacturers to maintain records of cleaning and sanitation and animal and pest control activities required under this section. These records would be required to include the date and time, the individual performing the activity, the type of activity performed, any information demonstrating the requirement was met, and any data or calculations necessary to reconstruct the results. We believe these records are necessary for tobacco product manufacturers to ensure that the required activities have been conducted and for FDA to verify that the activities have been adequately performed.

The proposed requirements for buildings, facilities, and grounds would help assure that the public health is protected by helping to prevent tobacco product contamination by, among other things, toxic cleaning compounds, inadequate maintenance, or cross-contamination from inadequate cleaning (*e.g.,* Refs. 42–44). Insanitary conditions can create the potential for growth of microorganisms that may render tobacco products injurious to health beyond what is normally associated with tobacco products (*e.g.,* Refs. 45 and 46).

These proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by helping to ensure that tobacco products are not ''prepared, packed, or held under insanitary conditions'' that may contaminate tobacco products and render them adulterated under section 902 of the FD&C Act. As discussed above, inadequate or inappropriate maintenance, cleaning and sanitizing procedures, or animal and pest control may result in conditions that can adulterate tobacco products.

3. Equipment

Proposed § 1120.36(a) would require finished and bulk tobacco product manufacturers to ensure all equipment is appropriately designed and constructed, and is suitable for its intended purpose. These proposed requirements are generally similar to the equipment controls in the industry recommendations and to controls that FDA has observed during establishment inspections. The term ''equipment'' means any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product. Equipment that is appropriately designed, constructed, and suitable for its intended purpose is designed and constructed in a manner that facilitates its function, use, maintenance, and cleaning. For example, under this proposal, a tobacco cutter would be required to be designed and constructed to enable use, cleaning, and maintenance (*e.g.,* inspection and replacement of its cutting blade). It would also be required to be suitable for its intended purpose to cut tobacco to particular specifications (*e.g.,* different cut sizes).

Proposed § 1120.36(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures, including the methods and schedules, for the routine cleaning and maintenance of equipment, to ensure proper performance of equipment and prevent contamination. This provision is intended to give each tobacco product manufacturer the flexibility to determine the appropriate methods and frequency of cleaning and maintenance of equipment based on their manufacturing practices. For example, a manufacturer may require that cutting equipment be cleaned after each batch of tobacco is produced, using approved sanitizing agents that will not contaminate the tobacco product. The manufacturer also could schedule maintenance involving disassembling, inspection, and replacement of the cutting blade to be performed every 6 months. Proposed § 1120.36(b) would also require that the procedures provide for any change-over of tobacco product and account for changes, limitations, or adjustment to the equipment. For example, if a manufacturer uses the same equipment to manufacture flavored and nonflavored tobacco products,[4] the cleaning and maintenance procedures must address the change-over activities to prevent mixups or cross-contamination (*e.g.,* Refs. 47 and 48).

Proposed § 1120.36(c) would require finished and bulk tobacco product manufacturers to identify (electronically, by signage, or other method of identification), if applicable, all processing lines and major equipment to be used during manufacturing to prevent mixups and contamination. The intent of this identification requirement is to prevent mixups (*e.g.,* flavored vs. nonflavored, regular vs. mentholated) and distribution of nonconforming product. FDA is also proposing that related information (*i.e.,* which major equipment and processing line was used in the manufacture of a batch of finished or bulk tobacco product) be maintained in the production record, pursuant to proposed § 1120.70(b)(3) to establish traceability and assist with, for example, nonconforming tobacco product investigations.

FDA recognizes that it is impractical to identify every piece of equipment used during manufacturing. Thus, the Agency proposes to require identification of major equipment only. Major equipment includes blending silos, conditioning cylinders, makers, filling machines, assembly equipment (for cartridge production), and packers. For example, if a manufacturer has multiple blending silos to hold different blends, conditioning cylinders at different stages that add different moisture levels, dedicated makers for different cigarette lengths/circumferences, filling machines for dry vs. moist snuff, and packers for soft vs. hard packs, this provision would require all such equipment to be appropriately identified. Examples of equipment that would not need to be identified under this proposed provision include a portable hand-held mixer, optical detectors (to remove foreign matter), metal detectors, string doffers (to remove string), and moisture meters/detectors. In addition, manufacturers would be required to identify all processing lines. For example, if there are dedicated maker and packer lines for regular and mentholated products, these processing lines would be required to bear appropriate identification to prevent mixups and contamination. If a

[4] FDA recently issued proposed tobacco product standards that would prohibit menthol as a characterizing flavor in cigarettes, 87 FR 26454 (May 4, 2022), and characterizing flavors (other than tobacco) in all cigars and their components and parts, 87 FR 26396 (May 4, 2022).

manufacturer does not have multiple or dedicated processing lines or major equipment that could lead to product mixup, it should document this as a justification for not implementing these proposed identification requirements.

Manufacturers may also choose to include in the identification of the processing line or major equipment the identification of the product being processed. FDA has observed that some manufacturers place designated, color coded, indicator to identify the flavor of the product (for example, pink for cherry flavor) being manufactured with that equipment. This requirement is intended to work in conjunction with the requirements for identification and acceptance status established in proposed § 1120.64. Identifying the product as well as major manufacturing equipment, will help minimize or eliminate mixups during the manufacturing process.

Proposed § 1120.36(d) sets out additional requirements for testing, monitoring, and measuring equipment. Testing, monitoring, and measuring equipment is used in all stages of manufacturing. Examples of testing, monitoring, and measuring equipment include pH meters, moisture meters, and weight or measurement scales that are used to verify established tobacco product specifications.

Proposed § 1120.36(d)(1) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for all testing, monitoring, and measuring equipment to ensure such equipment is capable of producing accurate and reliable results. For example, if a manufacturer uses a pH meter, this proposal would require procedures for the use of such a meter to address how its reference and pH electrodes are to be maintained in order to produce accurate results; otherwise, it could result in unstable and off-scale readings (Ref. 49). In addition, if an ingredient specification is measured by weight in grams, the scale would need to be sensitive enough to accurately and reliably provide these measurements to ensure the correct amount of the ingredient is added to the tobacco product.

Proposed § 1120.36(d)(2) would require that all testing, monitoring, and measuring equipment be identified and disabled, removed, replaced, or repaired when it is no longer suitable for its intended purpose or when it is no longer capable of producing accurate and reliable results. Defective equipment is not suitable for use in the manufacturing process and can result in nonconforming or contaminated tobacco product.

Proposed § 1120.36(d)(3) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the routine calibration of testing, monitoring and measuring equipment. Calibration provides assurance that equipment is properly performing and providing accurate and reliable measurements. Under this proposal, the procedures must describe an appropriate reference standard and include specific directions and acceptance criteria for the limits of accuracy and precision. Testing, monitoring, and measuring equipment must be calibrated before first use; thereafter, at a frequency determined by the equipment manufacturer or at intervals necessary to ensure accurate and reliable results; and after repair or maintenance. The appropriate frequency of calibration would likely depend on the particular equipment, the equipment manufacturer's recommendation, the activity the equipment is used for, and the individual calibration process. Calibration should be performed at suitable intervals in accordance with an established procedure containing specific directions, schedules, and limits for accuracy and precision based on the type of instrument being used and other factors such as operating environment and wear and tear.

Proposed § 1120.36(e) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Records would be required to include the date and time, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

The proposed equipment requirements would assure that the public health is protected, by helping to prevent the use of malfunctioning equipment that can produce nonconforming product. For example, if a tobacco cutter is not designed, constructed, or maintained properly, it can result in tobacco strips that do not conform to established specifications for cut size. The size of the cuttings of tobacco is a physical design specification that can influence the release of nicotine in a tobacco product (Ref. 6). Maintenance of equipment is also necessary to prevent contamination of tobacco product. For example, a finished tobacco product manufacturer previously recalled tobacco products due to heavy oil spots from a cutter head oil leak (Ref. 50). While some manufacturers may already have controls similar to the proposed requirements in place, FDA believes it is important that all manufacturers comply with these requirements to help protect against the manufacturing and distributing of contaminated or otherwise nonconforming product. The proposed identification requirement would help assure that the public health is protected by preventing mixups and contamination of tobacco products that could have an adverse impact on public health.

The proposed equipment requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, the equipment requirements would help ensure that tobacco products meet applicable statutory requirements under sections 905, 907, 910, and 911 of the FD&C Act. Equipment that functions properly and produces accurate and reliable results is necessary to ensure that new tobacco products and MRTPs are manufactured consistent with the specifications described in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA); that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics; and that tobacco products subject to tobacco product standards are manufactured in accordance with those standards.

For example, consider a cigarette product marketed pursuant to an SE Report. If laboratory equipment used in the cigarette manufacturing provides a check on the nicotine content in the manufactured products, improperly functioning equipment may allow higher nicotine content in the manufactured products. Such products would not conform to the specifications described in the SE Report. Because FDA authorizes the marketing of tobacco products based on the specifications described in the relevant marketing application, nonconforming products, such as the cigarette in this example, would be on the market without FDA authorization in violation of chapter IX of the FD&C Act.

In addition, a bulk manufacturer that does not properly maintain or calibrate its testing, monitoring, and measuring equipment can produce nonconforming bulk tobacco products. For example, cutting equipment that has not been properly maintained can result in bulk cigarette tobacco, RYO, or pipe tobacco products with an incorrect cut size. Similarly, filling equipment that has not been properly calibrated can produce bulk e-liquids with nicotine concentration that exceeds the labeled concentration.

4. Environmental Controls

Proposed § 1120.38(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to adequately control environmental conditions where appropriate. In addition, under the proposed requirement, environmental control systems would have to be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. Environmental control systems include associated equipment (*e.g.,* HVAC equipment, humidifier, air filters) that manages the facility's environmental conditions (*e.g.,* temperature, humidity, ventilation, filtration). These proposed requirements, which are intended to ensure that the tobacco product meets its specifications and is not adversely affected by environmental conditions, complement those in proposed § 1120.34, which are intended, in part, to ensure that buildings and facilities have adequate controls to prevent contamination. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001–2015 (Ref. 11).

The appropriate environmental control procedures needed to comply with this proposed requirement can vary by product, manufacturing process, and other factors. For example, if a tobacco product manufacturer uses a sterilization process for a moist snuff product to achieve a product stability specification, it should establish environmental controls for temperature, moisture, and time (Ref. 51). If a tobacco product manufacturer determines that specific conditions are necessary to minimize mold growth, it would need to establish appropriate environmental controls, such as controlling the relative humidity (Ref. 52). In addition, if an ENDS manufacturer determines that airborne particulates can contaminate e-liquids, appropriate environmental controls, such as use of air filters or precautions against potential sources of airborne contaminants, should be taken (*e.g.,* Ref. 10).

Proposed § 1120.38(a) also would require that environmental control systems be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. Monitoring of these systems can be performed by recording data, using alarms to determine if the environmental controls deviate from the operating range or fail, or other means to ensure that environmental controls are operating as intended.

Proposed § 1120.38(b) would require finished and bulk tobacco product manufacturers to maintain records regarding environmental controls, including maintenance and monitoring. Records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. We believe these records are necessary to ensure that the required activities have been conducted and for FDA to verify that the activities have been adequately performed.

The proposed environmental controls requirements would help assure that the public health is protected by maintaining proper environmental conditions to protect products from contamination and to ensure they meet specifications. For example, improper humidity and temperature during storage of tobacco can result in spoilage and the growth of mold (Ref. 53). Studies have shown that mold can grow on reconstituted tobacco at certain humidity and temperature conditions (Ref. 54). FDA is aware that some tobacco product manufacturers have a microbiological monitoring plan and perform environmental monitoring of water and air in accordance with that plan and assess the effectiveness of their sanitation procedures (Ref. 55). As an example of how environmental controls can also be important to ensure that products meet specifications, if a smokeless tobacco product uses a heat treatment process (Ref. 56) or a cigar uses a fermentation process (Ref. 57) to achieve a pH specification, the tobacco product would not conform to its established specification if the manufacturer does not establish and maintain environmental controls for the temperature, moisture, and time. As explained in more detail in the discussion of proposed § 1120.74 (see section II.E below), a specification such as pH can affect the speed and amount of nicotine that is delivered to a user (Refs. 6 and 19). Moisture and pH also can be associated with concentrations of nicotine in smokeless tobacco (Refs. 58 and 59). While some manufacturers may already have similar controls in place, this proposed rule would help ensure that all manufacturers establish such controls to help protect against the manufacturing and distributing of contaminated or otherwise nonconforming product.

In addition, the proposed environmental controls would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. As discussed, specific controlled environmental conditions may be necessary to manufacture a tobacco product that conforms to established specifications, including specifications described in any relevant tobacco product applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA), and to ensure that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics.

D. Design and Development Controls

1. Design and Development Activities

Proposed § 1120.42 addresses risks associated with design and development activities by requiring finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. Procedures to control the design and development of finished and bulk tobacco products would need to address risk management as well as design verification and validation. The proposed requirements incorporate principles similar to those found in, for example, ISO 9001; the QSR for medical devices; current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food; and HACCP regulations.

Proposed § 1120.42(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of each product and its package, including the control of risks associated with the product, production process, packing, and storage. While FDA is aware that some tobacco product manufacturers already engage in a wide variety of activities to control the design and development of tobacco products, including chemistry, toxicology, and nonclinical testing; clinical assessment and investigations; and consumer and market research (*e.g.,* Ref. 55), the Agency believes that these requirements are needed to ensure that all manufacturers address risks associated with design and development activities. A manufacturer's procedures may vary based on the type of tobacco product and may be specific to one or multiple products. Therefore, FDA is proposing a flexible framework to allow manufacturers to implement procedures that best suit their specific design and development approach.

Design activities can be performed by different parts of a tobacco product manufacturer's organization, (*e.g.,* manufacturing, marketing, purchasing, and regulatory affairs). Procedures to control the design and development of a tobacco product should establish the roles that any groups have in process and describe the information that they should receive and transmit, including any approvals that may be necessary.

Under proposed § 1120.42(a), design and development controls must control for risks associated with each finished and bulk tobacco product and its package, production process, packing, and storage. Specifically, proposed § 1120.42(a)(1) would require that the design and development procedures include a risk management process. For purposes of this rule, a risk management process is a preventive means to identify and control for potential risks throughout the product lifecycle (*i.e.,* during design, manufacturing, distribution, and use of products). Risk management is an established practice used by manufacturers in many industries, including in the manufacture of FDA-regulated products such as foods, drugs, biologics, and medical devices. General risk management standards such as ISO 31000:2018—Risk Management—Principles and Guidelines (Ref. 12) can be used by manufacturers to provide guidance in establishing and maintaining a risk management system. In some industries, industry-specific risk management standards have been developed (*e.g.,* Refs. 60 and 61), whereas other industries use a more broadly developed framework (*e.g.,* Ref. 62). While FDA is not proposing to require compliance with a particular risk management framework or standard, FDA recommends that finished and bulk tobacco product manufacturers use an established risk management framework such as a standard or guideline.

The proposed provision would give manufacturers flexibility in devising their risk management process and the type of risk assessment technique(s) employed; however, at a minimum, proposed § 1120.42(a)(1) would require that the risk management process include the following steps: risk assessment (including risk identification, risk analysis, and risk evaluation), risk treatment, and reassessment. A tobacco product manufacturer can perform their risk management process for categories, types, or families of products that share similar specifications and design characteristics. During inspections, the Agency has observed that some tobacco product manufacturers currently use a risk management framework (including, *e.g.,* HACCP plans) that is consistent with these proposed requirements (Ref. 63).

Under proposed § 1120.42(a)(1)(i), each finished and bulk manufacturer must perform a risk assessment that includes risk identification, risk analysis, and risk evaluation. Manufacturers can utilize various risk assessment techniques to help ensure compliance with this section, such as preliminary hazard analysis, Delphi, scenario analysis, fault tree analysis, cause-and-effect analysis, failure mode and effect analysis, hazard and operability studies, and hazard analysis and critical control points (Ref. 62). Risk assessment for risks associated with the tobacco product would need to be performed for each tobacco product manufactured, packed, or stored, taking into account the individual attributes of each product, its package, and manufacturing process. For example, a manufacturer performing a risk assessment for e-liquids would need to consider potential risks associated with access of e-liquid by children or leakage of e-liquid from cartridges during and after use, which can cause acute nicotine toxicity to users and nonusers.

The first step of risk assessment that would be required under proposed § 1120.42(a)(1)(i) is risk identification. At this step, manufacturers would be required to identify all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage (see Refs. 12 and 62). In identifying all known or reasonably foreseeable risks associated with the tobacco product, a manufacturer would be required to identify known or reasonably foreseeable risks that may occur naturally or be introduced, intentionally or unintentionally, in the growing, harvesting, curing, leaf processing, and warehousing of tobacco leaf, and during primary production, manufacturing, packing, or storage of finished or bulk tobacco products. These risks may include biological, chemical, or physical hazards in a tobacco product, such as harmful bacteria, pesticides, and NTRMs. Risk identification would also need to take into account risks associated with product design. An example of a risk associated with product design is a dissolvable tobacco product whose size and shape resembles candy, resulting in potential misuse by and harm to children.

''Known'' risks refer to those risks that a tobacco product manufacturer knows about through, for example, its manufacturing and distribution experience, records, and reports (such as complaints, returned products, nonconforming product, and CAPA). ''Reasonably foreseeable'' risks are those risks that a reasonably prudent tobacco product manufacturer would become aware of through scientific literature, publications, or public information, such as an industry standard or FDA guidance document. To identify risks, the manufacturer should evaluate relevant information, such as complaint file investigations, published literature, articles, and reports. For example, in identifying reasonably foreseeable risks associated with an ENDS product with a lithium battery, a manufacturer should take into consideration, among other things, available information regarding design features of lithium ion batteries that could cause overheating, fires, and explosions (*e.g.,* Refs. 64–69).

Proposed § 1120.42(a)(1)(i) would also require that risk identification include risks that may occur with normal use (*i.e.,* labeled and customary uses) and with reasonably foreseeable misuse (*i.e.,* any use not intended by the manufacturer, including user error) of a tobacco product. Risks that may occur with normal use and with reasonably foreseeable misuse are discussed in greater detail below.

The concept of ''reasonably foreseeable misuse'' is well-established and utilized in risk management. For example, the American National Standards Institute (ANSI)/Advancement of Medical Instrumentation (AAMI)/International Electrotechnical Commission (IEC) 62304:2006 regarding medical device software, states that manufacturers must identify potential causes of hazardous situations, including reasonably foreseeable misuse (Ref. 70). Since misuse of a product can be a source of harm, FDA believes it is appropriate to consider reasonably foreseeable misuse when completing risk management activities for tobacco products. An example of a risk related to reasonably foreseeable misuse would include a child accessing an e-liquid container that does not have a secure container closure system and ingesting the product, which could lead to serious injury or death due to nicotine toxicity.

Proposed § 1120.42(a)(1)(i) would require each finished and bulk tobacco product manufacturer to identify all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage. Risks associated with a tobacco product under proposed § 1120.42(a)(1)(i) would include risks associated with finished or bulk tobacco product specifications,

including product risks attributable to components or parts, ingredients, additives and materials; product design; and issues addressed in a tobacco product standard under section 907 of the FD&C Act. For example, use of an improper charger on a rechargeable e-cigarette may result in a battery fire or explosion due to differences in specifications. Similarly, use of e-liquid flavors containing diacetyl may cause acute-onset bronchiolitis obliterans, a severe and irreversible obstructive lung disease (Ref. 71).

Risk identification would also need to be performed for known or reasonably foreseeable risks associated with the tobacco product package. Risks associated with a tobacco product package would include substances that may render the contents injurious to health and cause the tobacco product to become adulterated under section 902(3) of the FD&C Act or a package design which can cause or expose users and nonusers to harm. For example, an e-liquid manufacturer would need to consider potential risks of leakage of e-liquid from cartridges, which can cause product malfunction (Ref. 72) or skin irritation (Ref. 73), as well as risks to nonusers such as children who can access the e-liquid and experience acute nicotine toxicity (Refs. 74–76).

Risk identification would also need to be performed for all known or reasonably foreseeable risks associated with the production process, packing, and storage. Risks associated with the production process, packing, and storage would include substances and conditions that can contaminate and/or render the tobacco product injurious to health and thereby cause the tobacco product to become adulterated under section 902(1) and (2) of the FD&C Act, including but not limited to, biological, chemical, and physical hazards described below. Risk identification should take into account the type of tobacco product being manufactured, the manufacturing processes, and the facility where the product is manufactured, packed, or stored. Risks identified in one facility may not be significant in another facility, even if it manufactures the same or a similar product, due to differences in equipment, process controls, and/or maintenance programs. Additionally, risks associated with a facility's tobacco products may differ based on the type of tobacco product manufactured, packed, or stored.

Risk identification should take into account biological, chemical, and physical hazards. For example, biological hazards such as bacteria, mold, yeast, microbes, and other biological organisms can grow on tobacco and tobacco products as a result of environmental conditions in their warehousing, packing, and storage. These hazards vary widely in their prevalence, mode of action, infectious dose, growth and survival specifications, and resistance to heating, chemical agents, and other processes or treatments. The Agency has observed on inspection that a cigarette manufacturer identified potential mold on incoming ''tobacco with yellow spots'' during visual inspection that was determined by microbiological analysis to be *Aspergillus flavus* (the major producer of aflatoxin, which is associated with an increased risk of liver cancer) (Ref. 77). In addition, microbes that can be found on tobacco and tobacco products include bacteria, bacterial spores, fungi (yeast and mold), fungal spores, cell wall components (certain glucans and flagellum), and diverse microbial toxins that include exotoxins and endotoxins (Ref. 78). Examples of bacterial-derived toxins include endotoxins (lipopolysaccharide, LPS; inflammatory factor) and mold-derived mycotoxins (Ref. 78).

Similarly, risk identification should include chemical hazards. Chemical hazards, including pesticide residues, can be naturally occurring or intentionally, unintentionally, or incidentally added to tobacco, tobacco products, or tobacco-product contacting surfaces. For example, pesticide chemical residues have been found on commercially available cigarettes. In 2003, the European Commission's Joint Research Centre investigated the content of organochlorine pesticides in a selection of commercially available cigarette brands and found that they contained pesticide chemical residues (Ref. 79). Organochlorine pesticides act on the nervous system to prevent the normal flow of nerve impulses to muscles that control both voluntary movement, such as walking, and involuntary movement, such as breathing and heartbeat (Ref. 80). These classes of pesticides are also associated with a range of adverse health effects that could result in immediate and life-threatening effects, such as respiratory failure, or conditions that do not appear immediately, such as cancer (Ref. 80).

When identifying chemical hazards, tobacco product manufacturers should assess the chemicals that are used in the manufacturing establishment for cleaning, sanitation, and pest control purposes that may be associated with the manufacturing, packing, and storage of tobacco products, including rodenticides, insecticides, fungicides, and fumigating agents. For example, FDA is aware of situations where packaging solvents, cleaning solutions, hydraulic oil leakage, and machine grease may have caused contamination (Refs. 50 and 81).

Risk identification should also take into account any physical hazards that may be associated with the tobacco product. These hazards include animals, animal parts and excrement, insects and insect excrement, such as tobacco beetles and insect parts; rocks, stones, and sand; plastic string, plastic sheet, foam, and rubber; metal, glass, hessian/burlap, wood products, cloth, and cotton strings; and other forms of NTRMs that may be introduced on the farm, during harvesting, and during the manufacturing process. The facility and equipment also can be a source of physical hazards (*e.g.,* metal fragments such as nuts and bolts from equipment used in manufacturing and processing, glass pieces from overhead light bulbs, or debris from overhead equipment). FDA is aware that glass shards have been found in smokeless tobacco products (Ref. 81). If glass is present in chewing tobacco, it may lacerate the gums or lips of the user of the tobacco product. FDA believes it is critical to identify NTRMs that may be introduced throughout the supply chain (Ref. 37).

FDA is proposing that the risk management process require identification of all known and reasonably foreseeable risks associated with the tobacco product, including risks that cause illness, injury, or death normally associated with the use of tobacco products. Identifying risks normally associated with the use of the tobacco product is necessary to perform an adequate risk analysis and evaluation. Some symptoms or health effects of risks not normally associated with the use of the tobacco product can be similar to the symptoms or health effects of risks normally associated with the use of the tobacco product, and therefore this requirement would help ensure that risks that may appear to be normally associated with the use of tobacco products, but are not, are included in the risk analysis and evaluation. In addition, identifying symptoms or health effects of risks normally associated with the use of the tobacco product and their likelihood and consequence of occurrence will help inform the investigation of user reports and complaints about such symptoms or health effects, because they may also point to risks not normally associated with the use of the tobacco product. For example, an increase of reported frequency or severity of respiratory distress from use of an ENDS product may help a

manufacturer detect a previously unidentified risk of metallic particles in the cartomizer aerosol due to defective solder joints from the cartomizer (Ref. 2). Similarly, increased complaints of pneumonia, exacerbation of asthma, bronchitis, chronic obstructive pulmonary disease, eosinophilic pneumonitis, and laryngitis may be associated with chemical contamination of a tobacco product (Ref. 82).

After risk identification, the next step of risk assessment is risk analysis. Risk analysis is an analysis of the nature and level of the risk for each identified known or reasonably foreseeable risk that takes into account the likelihood of occurrence of the risk and the consequences of occurrence of the risk (*i.e.,* severity of the potential harm). When considering the likelihood of occurrence of the risk, the manufacturer should consider the frequency that such risk may occur in the type of product, the production process, and the particular manufacturing establishment. When considering the consequences of the occurrence of the risk, the manufacturer should consider the health effects of the risk, including the severity, immediacy, or near-term onset of any potential injury or illness, and long-term effects from chronic or cumulative exposure, on both users and nonusers.

For example, FDA is aware that some manufacturers have identified styrene (Styrofoam) as a risk that requires risk control. Styrene is a chemical hazard that can be introduced in tobacco products as an NTRM such as via food containers that contaminate tobacco products during manufacturing or via a packaging coating that can be transferred to the tobacco product (Ref. 83). Styrene can enter into the body of consumers by inhalation or ingestion. Styrene consumption can affect the nervous system, resulting in changes in color vision, tiredness, feeling drunk, slowed reaction times, concentration problems, and balance problems (Ref. 84). The International Agency for Research on Cancer (IARC) has determined that styrene is a possible carcinogen (Ref. 85). Under the proposed rule, a manufacturer performing a risk analysis for styrene would consider the likelihood of styrene being introduced into the tobacco product and reaching consumers. It would also consider the health effects of styrene exposure on users and nonusers. For example, storage conditions such as temperature and duration can affect microbial growth and nitrite formation, which can influence tobacco-specific N-nitrosamines (TSNA) content in processed and packaged smokeless tobacco products. (*See* Ref. 16, Ref. 181–182). Under the proposed rule, a manufacturer should perform a risk analysis of the tobacco product using the expected storage period and conditions and determine the likelihood of changes to TSNA content that may result in an increased risk to public health as the product sits in storage.

Following risk analysis, the last step of risk assessment is risk evaluation. The proposed risk evaluation requirement would require an evaluation of each identified risk. Risk evaluation is a determination of the significance of the risk and the type of risk treatment needed (*e.g.,* avoiding the risk, mitigating the risk, or choosing to retain the risk), including the priority of the risk treatment. A comprehensive risk evaluation demonstrates that the manufacturer has considered all relevant information about the tobacco products being manufactured, packed, or stored and determined the significance of the identified risks and what type of risk treatment is needed.

In this context, determining the significance of the risk means evaluating whether the risk and its magnitude are acceptable, tolerable, or unacceptable. In determining the significance of the risk, manufacturers should develop criteria against which the risk and its magnitude can be evaluated. For example, a manufacturer may determine that, based on its risk criteria, a risk of nonusers ingesting e-liquids resulting in toxic nicotine exposure is not tolerable and must be controlled. The manufacturer may similarly determine that, based on its risk criteria, a nicotine concentration that is a certain percentage higher than the established specification is not tolerable and must be controlled through additional manufacturing controls such as acceptance testing. Determining the significance of a risk would inform the manufacturer's decision regarding what type of risk treatment is appropriate and the priority of that risk treatment. FDA is aware that during the evaluation stage of a risk assessment, manufacturers across industries sort risks into categories based on established risk criteria to determine whether risk control/mitigation is required, should be considered, or is not necessary (Ref. 12).

Proposed § 1120.42(a)(1)(ii) would require that each finished and bulk manufacturer treat all identified risks, including risks addressed in applicable tobacco product standards. Risk treatment can include implementing controls to avoid or remove the risk, or making an informed decision to retain the identified risk (Ref. 12). The proposed risk treatment requirements would require the manufacturer to significantly minimize or prevent risks identified in proposed § 1120.42(a)(1)(i) that are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or that the manufacturer determines constitute an unacceptable level of risk. Additionally, risks addressed in any applicable tobacco product standards would be required to be treated in a manner that ensures the tobacco product will conform to the specifications and requirements established in the tobacco product standard. FDA requests comment on whether these are the appropriate risks for which risk prevention or mitigation should be required.

FDA's application of risk management concepts acknowledges that the use and consumption of tobacco products entails some degree of risk inherent to tobacco use. Therefore, the risk mitigation and prevention requirements in the proposed rule focus on reducing or eliminating those risks associated with the tobacco product, its design and packaging, and its associated production process, packing, and storage that are reasonably likely to occur and may cause an illness, injury, or death not normally associated with the use of tobacco products. These requirements are also intended to address issues that the manufacturer determines constitute an unacceptable level of risk. This proposed provision would, therefore, require tobacco product manufacturers to, at a minimum, undertake risk treatment to significantly minimize or prevent such risks. Additionally, any risks identified in an applicable tobacco product standard would need to be treated in a manner that ensures the tobacco product will conform to the tobacco product standard.

For example, a manufacturer may determine that NTRMs such as glass, metal, rocks, and stones are introduced on the farm, during harvesting, or during the manufacturing process, and that, as a result, hard or sharp NTRMs are reasonably likely to occur in a tobacco product. The manufacturer may also determine that, when these hard or sharp NTRMs are present in a tobacco product, they may cause traumatic injury, including laceration and perforation of tissues of the mouth, tongue, throat, stomach, and intestine as well as damage to the teeth and gums. Based on this information, the manufacturer would be required to significantly minimize or prevent the risk under § 1120.42(a)(1)(ii) of the proposed rule.

Risk treatment measures will vary based on the type of product and the risks identified as well as the manufacturing facility. Risk treatment can include manufacturing controls, redesigning the tobacco product, clarifying user instructions, or ordering a component or part from a different supplier. Risk treatment also may include personnel requirements (*e.g.,* health, cleanliness, personal practices, and apparel of personnel), cleaning and sanitation controls, animal and pest controls, maintenance of equipment, environmental controls, purchasing controls (*e.g.,* Good Agricultural Practices, supplier guarantee, testing raw tobacco for pesticide chemical residues (Ref. 86)), acceptance activities (*e.g.,* visual inspection, tests, and other verification activities), and process controls (*e.g.,* metal detectors, x-rays, optical sorters). For example, FDA has noted on inspections that certain manufacturers have implemented manufacturing policies that include a requirement to use pens that do not have caps, are color-coded, and contain ferrous material to prevent physical hazards from being introduced in the tobacco product during the production process and enable the hazard to be readily identified by metal detectors and magnets if necessary (Ref. 87).

Where risk treatment measures required by proposed § 1120.42(a)(1)(ii) are implemented to significantly minimize or prevent a risk associated with the production process, packing, and storage that is reasonably likely to occur and may cause serious illness, injury, or death not normally associated with the use of the tobacco product and package, or that the manufacturer determines constitutes an unacceptable level of risk, the manufacturer should incorporate these measures in the relevant procedure(s) under proposed part 1120. For example, the manufacturer may need to incorporate the risk treatment measures into its procedures for personnel practices under proposed § 1120.32, buildings, facilities, and grounds under proposed § 1120.34, environmental controls under proposed § 1120.38, purchasing controls under § 1120.62, acceptance activities under proposed § 1120.64, and production processes and controls under proposed § 1120.66. Manufacturers also would be required to validate or verify their production process in accordance with proposed § 1120.66.

A manufacturer may determine that a risk is unacceptable if it occurs infrequently but the consequences are severe. Likewise, a risk may be unacceptable if the risk occurs frequently, even if it is not associated with serious illness or injury. For example, if a cigarette manufacturer uses a new filter supplier that uses methyl isothiocyanate (which can cause throat irritation) in its filter processing, it may determine that this is an unacceptable level of risk if it occurs frequently, even though the severity of the risk is moderate or low.

Although testing alone is rarely considered an effective risk treatment, testing can be useful to verify that control measures are effectively minimizing or preventing risks. For example, microbial testing of raw materials may verify that suppliers have controlled for biological hazards. Environment testing also may verify whether sanitation or environmental controls have addressed the potential for environmental pathogens to contaminate tobacco products. For example, during acceptance moisture testing, a manufacturer may determine a finished product has excessive moisture content during the packing process that has resulted in spoilage of cigarettes due to growth of *Aspergillus restrictus* and *Aspergillus glaucus* mold, a biological hazard (Ref. 88).

Where a manufacturer has identified a risk associated with consumer misuse of a product, the manufacturer may need to redesign the product in order to comply with this proposed provision. If there is a potential for misuse that causes harm and such misuse could be prevented, the manufacturer should address it. For example, a tobacco product manufacturer may determine that a package redesign could reduce choking hazards associated with dissolvable tobacco products or toxic exposure to e-liquids (*e.g.,* Refs. 89 and 90). Similarly, an ENDS manufacturer could redesign a battery charger connection if the manufacturer identifies the risk that users are misusing the USB charging connection port and using a nonstandard USB power source that does not match the manufacturer's specifications. Depending on the manufacturer's assessment of the risk, a redesign may not always be necessary. However, if new information suggests that risk treatment short of redesign has not been effective, the proposed rule would require the manufacturer to reassess their risk treatment activities pursuant to proposed § 1120.42(a)(1)(iii) and consider additional mitigation.

Proposed § 1120.42(a)(1)(iii) would require each finished and bulk tobacco product manufacturer to reassess the risks whenever the manufacturer becomes aware of new information that could change the risk assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures.

The risk management process FDA is proposing is an ongoing process whereby manufacturers update their risk assessment as new information is learned. The purpose of the reassessment requirement is to determine if existing risk assessment and risk treatment need to be updated in light of new information that bears on the effectiveness of the risk management process. New information can inform the scientific understanding of a previously assessed risk or identify a new risk. A finished or bulk tobacco product manufacturer may become aware of new information in a variety of ways, including user and nonuser reports of adverse experiences, records and reports (such as complaints, returned products, nonconforming product, and CAPA), and through scientific literature, publications, or public information, such as an industry standard or FDA document.

Proposed § 1120.42(a)(1)(iii) would specifically require finished and bulk tobacco product manufacturers to reassess risks whenever the manufacturer becomes aware of new information that indicates a previously unidentified risk. For example, an ENDS manufacturer may become aware that the ENDS product's power settings can result in carbonyl generation which can increase cancer potency (Refs. 91 and 92). Under these circumstances, the ENDS manufacturer would have to undertake the risk assessment and risk treatment steps for the newly identified risk.

Additionally, this provision would also require the manufacturer to reassess the risks when it becomes aware of new information that indicates that a previously identified risk they did not believe was reasonably likely to occur is, in fact, reasonably likely to occur. For example, a tobacco product manufacturer may have previously identified metal fragments in chewing tobacco as a risk that was not reasonably likely to occur. If the manufacturer begins to receive consumer complaints about metal fragments being found in its chewing tobacco, this new information would necessitate a reassessment of the risk to determine whether the initial risk analysis and evaluation must be updated and new risk treatment measures must be implemented.

In addition, this provision would also require manufacturers to reassess risks when they become aware of new information that indicates the existing risk treatment measures are ineffective.

For example, if consumer complaints report that finished tobacco products continue to have NTRM after risk treatment measures have been implemented, the tobacco product manufacturer would need to reassess the risk and modify the treatment measures as necessary.

FDA recognizes that batteries and other components may be a source of risk. Therefore, FDA is proposing that finished and bulk tobacco product manufacturers, which are responsible for component selection and design (*e.g.,* an ENDS manufacturer responsible for the selection of the battery and the manner in which it operates in the ENDS product), would need to do a risk assessment of the risks associated with the finished or bulk tobacco product, including risks attributable to such components. For example, an ENDS manufacturer should perform a risk assessment of the battery design (such as an internal or a commercially available off-the-shelf external battery), safety rating, and suppliers to consider potential risks associated with use of the battery with their ENDS product that may occur during normal use (*e.g.,* charging) and during reasonably foreseeable misuse (*e.g.,* customer replacement with a non-OEM battery).

FDA is aware that not all tobacco product manufacturers design the tobacco products they manufacture. Under this proposed rule, contract manufacturers who are not responsible for product design would not be required to assess the design risks associated with the products' specifications. For example, if a contract manufacturer does not engage in design activities but only manufactures a tobacco product for another party based on specifications provided by that party, the contract manufacturer would not be responsible for assessing the design risks associated with the product's specifications.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(2) would require finished and bulk tobacco product manufacturers to perform design verification to confirm that the tobacco product and its packaging meet specifications and design validation to assess the performance of the tobacco product. These activities would be informed by the risk management process in proposed § 1120.42(a)(1). Process verification and process validation would be separate requirements and are found in proposed § 1120.66. Design verification confirms that the product and packaging meet their specifications. Design verification activities can include testing and studies, and reviewing design documents before their release as specifications in the MMR. For example, an ENDS manufacturer may establish that the specification for a battery is a power of 4 volts, temperature range of 200 °C to 300 °C, it must be charged in less than 90 minutes, and that it can be recharged 1,000 times. Under the proposed rule, the manufacturer would be required to perform battery testing to verify that the battery performance meets those specifications.

Design validation is a process to assess the product performance to confirm that it consistently performs or functions as intended. For example, a manufacturer could perform testing of child resistant packaging to validate the effectiveness of the package design in preventing children from accessing the tobacco product while allowing adult users to open the package.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(3) would require that the product and packaging design be approved by a designated, authorized individual. The review and approval would be required to ensure that the product and packaging specifications are supported by the product design verification and validation activities and that appropriate risk treatment measures have been implemented.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(4) would require finished and bulk tobacco product manufacturers to transfer the approved product and packaging specifications to the MMR. Proposed § 1120.42(a)(5) would require finished and bulk tobacco product manufacturers, where appropriate, to utilize the processes under proposed § 1120.42(a)(2) through (4) for design changes before the changes are implemented.

Proposed § 1120.42(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. These records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. Manufacturers would have flexibility to determine the format in which these records are maintained. For example, these records may be maintained in a single record or single file of records, or as part of a product- or product-type-specific index system that references and includes the location of all the required information. The results of the design and development activities would produce the information documented in the MMR, including specifications, manufacturing methods and procedures, and packaging and labeling (see proposed § 1120.44(a)).

The proposed requirements for design verification and validation, design approval, and design transfer under § 1120.42(a)(2) through (4) would not apply to existing tobacco products already commercially marketed before the effective date of this rule, including, for example, pre-existing tobacco products commercially marketed in the United States as of February 15, 2007. Finished and bulk tobacco product manufacturers would not be required to perform retroactive design verification to confirm that such tobacco products and their packages meet specifications, or retroactive design validation to assess their performance. Similarly, finished and bulk tobacco product manufacturers would not be required to perform retroactive design approval and design transfer for such products under proposed § 1120.42(b)(3) and (4). However, the proposed § 1120.42(a)(2)–(4) requirements would apply to finished and bulk tobacco products first commercially marketed after the effective date of the rule, and to any finished and bulk tobacco products that are modified after the effective date of the rule, including changes made in order to comply with a tobacco product standard. When changes are made to finished or bulk tobacco products commercially marketed before the effective date of any final TPMP rule, the proposed requirements of § 1120.42(a)(2) must be followed to confirm that the tobacco product and its package, as modified, meet specifications and that the tobacco product will perform as intended.

The proposed design and development activities requirements would help assure that the public health is protected by helping to prevent illness, injury, or death not normally associated with the use of the tobacco product, including to users and nonusers. The proposed provisions would require finished and bulk tobacco product manufacturers to perform an assessment of the known and reasonably foreseeable risks associated with the tobacco product, its package, and its production process, packing, and storage that may occur with normal use of the tobacco product or with any reasonably foreseeable misuse of the product, including user error. For

example, ENDS can overheat, resulting in fires and explosions (*e.g.,* Refs. 64, 93 and 94). Under these proposed requirements, an ENDS manufacturer would be required to assess the risk the battery poses in the design of its finished tobacco product, as lithium batteries can contribute to ''thermal runaway'' and cause a battery fire or explosion (Ref. 67). If the ENDS manufacturer determines that this risk is reasonably likely to occur and that it may cause serious illness, injury, or death not normally associated with the use of the tobacco product, it would then be required to take appropriate treatment measures to significantly minimize or prevent the risk, such as use of overcharging protection circuits, thermal power cutoffs, and internal overpressure relief mechanisms that can help prevent and mitigate thermal runaway. The proposed provision would then require manufacturers to verify and validate the design of the product taking into account these risk treatment measures.

FDA believes that engaging in a risk management process is the most effective and efficient way to proactively ensure that risks associated with finished and bulk tobacco products, their package, and their production process, packing, and storage, are adequately assessed and treated. FDA believes such an approach is more effective than identifying and controlling risks through finished product testing or sanitation controls alone (Ref. 95). Additionally, other TPMP requirements such as product complaints, acceptance activities, nonconforming product, and returned product may not be sufficient to address all risks.

The requirement to maintain records of required design and development activities could help FDA understand how a tobacco product manufacturer has established the specifications in the MMR for the finished or bulk tobacco product and their impact on public health. In addition, in the event of a recall, FDA could use these records to learn information that may be related to the recall and ascertain the appropriate way to address the issue. For example, FDA is aware of instances where contamination of cigarettes with a suspected chemical hazard resulted in a recall. One cigarette manufacturer announced a voluntary recall of approximately 8 billion cigarettes because the company detected unusual tastes and peculiar odors in 36 product lines (Ref. 82). Consumers who smoked the affected cigarettes reportedly suffered from pneumonia, exacerbation of asthma, bronchitis, chronic obstructive pulmonary disease, eosinophilic pneumonitis, and laryngitis (Ref. 82). The manufacturer detected methyl isothiocyanate (MITC) in the cigarette filters (Ref. 82). Adverse health effects from MITC exposure (*e.g.,* mucosal irritation of the respiratory and gastrointestinal tracts, conjunctival irritation, and neurologic symptoms) have been documented, although it was not established in this recall event that the reported illnesses were associated with users smoking contaminated cigarettes (Ref. 82). In such a scenario, if MITC was not previously an identified risk but was subsequently determined to pose a risk because it was used in the production of cigarette filters by the filter supplier, this provision would have required the manufacturer to reassess the risk and to take appropriate risk treatment steps. The risk assessment and risk treatment steps could include notifying the filter supplier to cease the use of this substance to minimize or prevent this risk if the manufacturer determined the level of risk to be unacceptable. Alternatively, the manufacturer could use the updated risk assessment to choose an alternate filter supplier who does not use MITC in the manufacture of filters.

The proposed design and development activities requirements also would help assure that the finished or bulk tobacco product is in compliance with the requirements of chapter IX of the FD&C Act. For example, finished or bulk tobacco products that pose risks such as physical, chemical, and/or biological hazards may be adulterated under section 902 of the FD&C Act. While some finished and bulk tobacco product manufacturers may already have similar controls in place, FDA believes that manufacturers should be required to engage in a risk management process and perform design validation and verification to help protect against the manufacture and distribution of nonconforming and/or contaminated product.

3. Master Manufacturing Record

Proposed § 1120.44(a) would require finished and bulk tobacco product manufacturers to establish and maintain an MMR for each finished and bulk tobacco product they manufacture for distribution. These proposed requirements are similar to those in other FDA-regulated industry manufacturing regulations (*e.g.,* § 820.181). An MMR is a document or a designated compilation of documents containing the established specifications for a tobacco product, including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product.

Under proposed § 1120.44(a)(1), the MMR must include the tobacco product specifications and acceptance criteria for those specifications. A tobacco product specification is any requirement established by the manufacturer (including specifications necessary to ensure that the tobacco product meets any applicable product standard) with which a product must conform. Tobacco product specifications can include physical, chemical, and biological specifications. Examples of physical specifications include length, circumference, and pressure drop for cigarettes and cut size and weight for smokeless tobacco products. An example of a chemical specification is a pH level for smokeless tobacco products, and an example of a biological specification is a specification related to the use of a biological fermentation agent used during the manufacturing process for smokeless tobacco products.

Tobacco product specifications in the MMR could include specifications for the finished or bulk tobacco products as well as specifications for incoming components and in-process tobacco products. For example, a tobacco product manufacturer may establish specifications for the cut size of incoming tobacco cut filler or the length, diameter, and tow of incoming filters. Tobacco product manufacturers may also establish specifications for in-process tobacco products, for example, a specification for the pH of fermented tobacco before it is packaged as a finished smokeless tobacco product or a specification for the length, circumference, and pressure drop of cigarette filter rods before they are packaged as finished cigarettes. In addition, tobacco product manufacturers may establish specifications for finished tobacco products, for example, specifications for the length, circumference, and pressure drop for cigarettes, or cut size and weight for smokeless tobacco products.

Proposed § 1120.44(a)(1) also would require that the MMR include acceptance criteria for the tobacco product specifications. The acceptance criteria should indicate if there is a particular value, range, minimum or maximum value, and/or standard deviation associated with a specification for an incoming component, in-process product, or finished or bulk tobacco product. For example, if a smokeless

tobacco product manufacturer establishes a pH and a weight specification for a finished smokeless tobacco product, proposed § 1120.44(a)(1) would require that the MMR for the product indicate the specific pH and weight acceptance criteria, for example, 7.2 ±0.5 pH and 3g ±0.2 gram (g), respectively. Similarly, if an ENDS manufacturer establishes a voltage specification for an adjustable, variable voltage product, the MMR would have to indicate the voltage acceptance criteria, for example, a range of 3–6 V. While this proposed rule would require acceptance criteria, the tobacco product manufacturer would determine the specific acceptance criteria that are appropriate for each established specification.

Under the proposed requirement, it would generally be up to manufacturers to determine what specifications to include in the MMR for each particular product they manufacture. However, proposed § 1120.44(a)(1)(i) through (iv) would require that, at a minimum, tobacco product specifications in the MMR include certain specifications related to product content, design, any applicable product standards established by FDA under section 907 of the FD&C Act, and pesticide chemical residues for raw tobacco.

Proposed § 1120.44(a)(1)(i) would require the product specifications in the MMR to include the identity and amount of any components or parts, ingredients, additives, and materials in the finished or bulk tobacco product. This information could be presented, for example, in a bill of materials that describes the identity and amount of the ingredients, additives, and materials in a finished tobacco product. The identity of all components or parts, ingredients, additives, and materials in the finished or bulk tobacco product should include a uniquely identifying name and/or number information. The proposed approach for uniquely identifying information is intended to be consistent with FDA's current thinking on listing of ingredients under section 904 of the FD&C Act as articulated in FDA's guidance entitled ''Listing of Ingredients in Tobacco Products.'' For example, for ingredients that are single chemical substances, uniquely identifying information should be a unique scientific name or code, such as the FDA Unique Ingredient Identifier code, Chemical Abstracts Service number, or International Union of Pure and Applied Chemistry name. Leaf tobacco (*i.e.,* whole leaf or parts) that has been prepared solely by mechanical processing that involves no chemical, additive, or substance other than potable water should be uniquely identified by, if known: the type (*e.g.,* burley, bright, oriental); the variety; the cure method (*e.g.,* flue, fire, sun, steam, air) and heat source (*e.g.,* propane, wood); and a description of any recombinant DNA technology used to engineer the tobacco. Complex purchased ingredients, as described in FDA's revised guidance, ''Listing of Ingredients in Tobacco Products,'' should be identified by: the complete name of the manufacturer of the complex purchased ingredient and the uniquely identifying item name and/or number (*e.g.,* catalog number or Universal Product Code (UPC)) used by that manufacturer. Complex ingredients made by the tobacco product manufacturer or made to the tobacco product manufacturer's specifications should be included in the MMR in a manner that uniquely identifies each individual ingredient.

We recognize that some tobacco product manufacturers obtain certain components or parts for their products from other manufacturers or suppliers and may not be in a position to know every individual ingredient in those components or parts. This is especially true if the component or part is, for example, a proprietary blend. In these instances, the tobacco product manufacturer could comply with proposed § 1120.44(a)(1)(i) by including the complete name of the manufacturer of the component or part and a uniquely identifying item name and/or number (*e.g.,* catalog number or UPC) used by that manufacturer. The tobacco product manufacturer, however, would have to comply with additional requirements intended to ensure awareness of any changes to purchased components or parts that may affect the tobacco product (see proposed § 1120.62(c), *Purchasing controls*).

Proposed § 1120.44(a)(1)(ii) would require the MMR to include the finished or bulk tobacco product design, meaning the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product. For example, a cigarette's design could include design features such as ventilation, paper porosity, tobacco cut width, and filter efficiency and the manner in which the tobacco cut filler, filter, cigarette paper, tipping paper, and plug wrap are assembled to produce a finished cigarette.

Under proposed § 1120.44(a)(1)(ii), a manufacturer must also include an identification of the product's heating source, if any (*e.g.,* burning coal, electric, chemical reaction, carbon tip), a discussion of the intended user operation (how the tobacco product will be used or operated by a user), and any relevant product drawings or schematics. For example, a discussion of the intended user operation of an ENDS product could include the appropriate and intended methods to charge the ENDS battery or how to handle, refill, and store the e-liquids for the ENDS product.

Proposed § 1120.44(a)(1)(iii) would require the MMR to include any specification necessary to ensure that the tobacco product meets any applicable product standard established under section 907 of the FD&C Act. For example, under section 907 of the FD&C Act, FDA could establish a product standard requiring the reduction of an additive or constituent in a tobacco product. In this case, the tobacco product manufacturer would be required to include any specification necessary to ensure that the product meets the established standard for that additive or constituent. Finally, proposed § 1120.44(a)(1)(iv) would require the MMR to include specifications for pesticide chemical residues for raw tobacco.

Proposed § 1120.44(a)(2) would require the MMR to include all relevant manufacturing methods and production process procedures. This requirement is intended to capture all the manufacturing steps involved in making the tobacco product, from receipt of incoming materials to distribution of the finished or bulk product. Under this requirement, the tobacco product manufacturer would be required to include any process controls, production process specifications with relevant acceptance criteria, and monitoring and acceptance activities (inspections, testing, evaluation, and other verification activities). For example, a smokeless tobacco product manufacturer may control its fermentation process by using a specific amount of a biological agent, controlling temperature and humidity, and setting turn cycle specifications. Under the proposed requirements, the manufacturer must include these production process specifications and activities in the MMR for the finished or bulk tobacco product. The manufacturer would also be required to include any established acceptance criteria associated with these activities and process specifications, for example, acceptable temperature and humidity ranges for the fermentation process.

The manufacturing methods and production process procedures in the MMR would also be required to include any monitoring and acceptance

activities. These are the activities the manufacturer performs to ensure that the production process meets the established process specifications. Acceptance and monitoring activities may include inspections, tests, evaluation, and other verification activities. Under proposed § 1120.44(a)(2), the manufacturer would be required to document all these activities in the MMR.

Specific aspects of the requirement in proposed § 1120.44(a)(2) and related requirements are further discussed in the proposed sections that follow, including proposed §§ 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls).

Proposed § 1120.44(a)(3) would require the MMR to include all packaging, labeling, and labels approved by the manufacturer for use with the finished or bulk tobacco product. To satisfy this requirement, a tobacco product manufacturer could maintain actual copies of the packaging, labeling, and labels approved for use with the finished and bulk tobacco products. Alternatively, a manufacturer could maintain artwork files that describe the design, layout, and content of the packaging, labeling, and labels approved for use with the products. For example, a finished tobacco product manufacturer may have packaging and labeling materials with different warning statements or different product package inserts or onserts. Under the proposed requirement, the MMR for the finished tobacco product would have to include or reference the location of these materials so that they can be readily accessible to FDA during inspections.

The MMR could be prepared either as a single document (or single file of documents) or as a product-specific index system that references and includes the location of all the required information. For example, if a specific manufacturing procedure is relevant to multiple tobacco products, the manufacturer would not need to reproduce that procedure in the MMR file for each product; instead the MMR file for each product could simply list and cross-reference the procedure (*e.g.,* identify it by a name and/or number) and indicate where the procedure can be found. Similarly, MMR files for multiple products could be included in one single document, as long as it is clear from the document what information pertains to each specific finished or bulk tobacco product.

Proposed § 1120.44(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the review and approval of the MMR, including any changes made to the MMR after initial approval. Under these procedures, a designated, qualified individual would be required to review and approve all MMR information before it is implemented in the manufacture of finished or bulk tobacco products for distribution. The designated, qualified individual's approval of the MMR would be required to be documented by date of approval and name and signature of the individual(s) approving the document.

When reviewing and approving the MMR for a tobacco product, the designated, qualified individual would be required to confirm that any design activities conducted to support the tobacco product specifications have been completed in accordance with the product design and development procedures established by the manufacturer under § 1120.42 and that the resulting production specifications are correctly transferred into the established MMR. These proposed requirements are intended to ensure that the tobacco product manufacturer has adequate control over the MMR, including changes to the MMR, and therefore over the product, prior to its release for distribution.

Proposed § 1120.44(c) would require that the MMR describe which methods and procedures established under § 1120.44(a)(2) and related sections, including §§ 1120.62 (Purchasing controls), 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls), are used to ensure that the tobacco product is manufactured in conformance with each tobacco product specification established under § 1120.44(a)(1). Thus, under proposed § 1120.44(a)(1), the MMR would include all established product specifications; under proposed § 1120.44(a)(2), the MMR would include all relevant manufacturing methods and production process procedures; and under proposed § 1120.44(c), the MMR would link the methods and procedures with the specifications by indicating which method or procedure would be used to ensure that each particular specification is met.

For example, under proposed § 1120.44(a)(1) a finished cigarette manufacturer may establish specifications for the porosity, ink type and color, and burn properties of a cigarette paper. If the manufacturer receives the paper from a qualified cigarette paper supplier (consistent with the purchasing controls in proposed § 1120.62) and ensures that the paper meets its specifications by relying on a Certificate of Analysis (CoA) from the supplier that addresses these specifications, under proposed § 1120.44(c), the manufacturer would be required to indicate in the MMR that a supplier's CoA is used to ensure that the cigarette paper meets specifications for porosity, ink type and color, and burn properties. Similarly, a smokeless tobacco product manufacturer may use a laboratory test as its acceptance activity (consistent with the acceptance activity requirements in proposed § 1120.64) to ensure that a smokeless product meets its pH specification, or a cigarette manufacturer may use a validated cutting process (consistent with the production processes and controls in proposed § 1120.66 and laboratory controls in proposed § 1120.68) to demonstrate that the tobacco cut filler meets its cut size specification. Under proposed § 1120.44(c), the manufacturers would be required to indicate the link between these activities and controls and the tobacco product specifications in the MMR.

The Agency believes that the proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. The proposed requirements would accomplish this by requiring manufacturers to establish specifications for each finished or bulk tobacco product and follow manufacturing methods and procedures that ensure that those specifications are met and, therefore, that products are manufactured in a controlled and consistent manner. The proposed MMR requirements provide a foundation for several of the requirements in part 1120. Building on the specifications established in the MMR, the purchasing controls, acceptance activities, process controls, and production record requirements would help ensure that each batch of tobacco product is manufactured in conformance with its established specifications. A manufacturer that fails to maintain control over its production process could manufacture and distribute nonconforming tobacco products, which could adversely affect public health. Because the MMR forms the foundation for the process controls that ensure that the production process operates as intended, the proposed MMR requirements would help ensure that nonconforming tobacco products are not manufactured and released for distribution.

Under the proposed MMR requirements, manufacturers would be required to establish specifications

related to the content and design of their finished and bulk tobacco products. Content and design are two critical parameters of finished and bulk tobacco products that can have a direct effect on public health. The physical design specifications of a tobacco product interact with its chemical composition to influence its function and effect on consumers. Thus, the content and design of finished and bulk tobacco products can impact the health consequences and addictiveness of the product. For example, the design of a cigarette filter's ventilation impacts the level of tar, nicotine, and carbon monoxide produced in the cigarette's smoke (Ref. 96). If a cigarette deviates from this ventilation design, the amount of tar, nicotine, and carbon monoxide delivered to the user may vary, affecting the tobacco product's toxicity and addictiveness. Because the content and design of a tobacco product can directly (*e.g.,* by increasing harmful emissions) or indirectly (*e.g.,* by increasing the addictiveness and the amount of use) contribute to the harm of a product, tobacco products that are manufactured inconsistently with established specifications may cause increased harm to the public health beyond what is normally associated with the product (Ref. 6). Requiring manufacturers to establish product specifications and manufacture products that meet those specifications helps minimize harm to public health associated with nonconforming products.

In addition, the Agency believes that the proposed MMR requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, the proposed requirements would enable the Agency to monitor and confirm that tobacco products are not manufactured in a manner that causes them to become adulterated or misbranded in violation of section 902(1) through (3) or 903 of the FD&C Act.

By requiring manufacturers to establish product specifications and manufacturing methods and procedures, the proposed requirements would reduce the chances of adulteration during the production process. For example, maintaining a state of control would help decrease the likelihood that products contain filthy, putrid, or decomposed substances, or are otherwise contaminated by added poisonous or deleterious substances that may render the product injurious to health. A controlled production process would also help ensure that products are not prepared, packed, or held under insanitary conditions.

The proposed MMR requirements, in particular proposed § 1120.44(a)(3), would also help ensure that the packaging, labeling, or labels of finished tobacco products comply with applicable statutory and regulatory requirements. For example, the packaging and labeling information maintained in the MMR would help FDA ascertain whether manufacturers are adulterating or misbranding products by approving and using packaging or labeling that is false or misleading, lacks required health warnings, or contains unauthorized modified risk claims.

The proposed MMR requirements, together with the proposed process controls, also would enable tobacco product manufacturers to ensure, and FDA to verify, that tobacco products are manufactured in compliance with the applicable premarket requirements under sections 905 and 910 of the FD&C Act. Specifically, the proposed requirements would enable FDA to verify that the established specifications for new or MRTPs are consistent with the tobacco product specifications provided by the manufacturer to FDA in the relevant tobacco product applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that the specifications for pre-existing tobacco products are consistent with their original characteristics. The proposed MMR requirements would also help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to tobacco products that may render the products new and adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act.

The MMR requirements would also help ensure that tobacco products are manufactured in compliance with any tobacco product standards established under section 907 of the FD&C Act. Under section 907, the Agency can adopt a tobacco product standard if it finds that the standard is appropriate for the protection of the public health. Proposed § 1120.44(a)(1)(iii) would require the manufacturer to establish in the MMR any specifications necessary to ensure that the tobacco product meets any applicable product standard. For example, under section 907, FDA could require a reduction or elimination of an additive or constituent. In such an instance, proposed § 1120.44(a)(1)(iii) would require manufacturers to establish specifications in the MMR to ensure that the additive or constituent is reduced or eliminated in accordance with the standard.

E. Process Controls

1. Purchasing Controls

Proposed § 1120.62 would require manufacturers to ensure that purchased or otherwise received products and services from suppliers conform to established specifications and that suppliers are qualified. Specifically, proposed § 1120.62(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that each purchased or otherwise received product or service related to the manufacture of a finished or bulk tobacco product is from a qualified supplier and conforms to established specifications. In this context, ''products or services related to the manufacture of a finished or bulk tobacco product'' means products or services that are used in the manufacture of the product or that could impact the performance, composition, constituents or characteristics of the product.

A purchased or otherwise received product related to the manufacture of a finished or bulk tobacco product would include a component or part, ingredient, additive, or other material purchased or received for use in the manufacture of a finished or bulk tobacco product. It also would include manufacturing materials as well as other materials purchased or received for use in the manufacture, packing, and storage of tobacco products, on tobacco product contact surfaces, or for the manufacturing operation, including cleaning and sanitation, of buildings, facilities, and grounds.

A supplier of such product may be internal (from an establishment within the manufacturer's organization; *e.g.,* a sister facility) or external (from an entity outside of the manufacturer; *e.g.,* an external third-party entity that supplies tobacco blends or flavorings). For example, a cigarette manufacturer may establish filter specifications for circumference, length, and pressure drop in the MMR in accordance with proposed § 1120.44(a)(1) and purchase filters from an external supplier. The proposed purchasing controls provision would require that the cigarette manufacturer establish and maintain procedures to ensure that the filter supplier is qualified and that the filters purchased and received from the external filter supplier conform to the established specifications. Such purchasing control procedures would be required whether payment for the products or services occurs or not. Thus, for example, a cigarette manufacturer would be required to comply with these requirements even when it receives

filters from an internal supplier, such as a ''sister facility'' or another corporate or financial affiliate.

A ''purchased or otherwise received service related to the manufacture of a finished or bulk tobacco product'' would include any activity associated with a manufacturing method or production process procedure established in § 1120.44(a)(2) as well as any activity regulated under proposed part 1120. Such services would include manufacturing or other activities (*e.g.,* specification development, laboratory testing, packaging and labeling) that are contracted to others. For example, a tobacco product manufacturer may contract with a third-party laboratory to perform laboratory tests, or contract with others to perform certain activities required under proposed part 1120, such as complaint handling, facility cleaning, or pest control. Purchasing controls for such outsourcing services would be an additional requirement to help ensure that any service purchased or otherwise received from a supplier complies with the relevant requirements in proposed part 1120 (*e.g.,* §§ 1120.44(a)(2), 1120.68, 1120.14, 1120.34) and meets specified requirements. In such cases, the finished or bulk tobacco product manufacturer would still be responsible for complying with all applicable requirements under proposed part 1120, even though it has chosen to outsource certain activities.

Proposed § 1120.62(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for qualifying their suppliers. It is important that suppliers be qualified to demonstrate their ability to provide products and services to tobacco product manufacturers that meet established specifications. Proposed § 1120.62(b)(1) would require the qualification procedures to include evaluating and selecting potential suppliers based on their ability to meet requirements set by the manufacturer in writing (on paper or electronically). Supplier evaluation and selection may be based, in part, on a supplier's past performance (*i.e.,* a supplier's historical ability to meet a manufacturer's specifications or requirements consistently). Qualification could also include onsite visits, audits of the supplier's practices or records, or periodic testing or sampling of the supplier's products or services to determine if they conform to established specifications and if the supplier complies with applicable requirements under proposed part 1120. It would be the finished and bulk tobacco product manufacturer's responsibility to establish the appropriate supplier evaluation and selection process to ensure that purchased or otherwise received products and services related to the manufacture of a finished or bulk tobacco product meet established requirements.

Proposed § 1120.62(b)(2) would require the qualification procedures to include provisions that define the type and extent of control to be exercised over selected suppliers and their product or service, based on evaluation results. Manufacturers should determine the degree of control necessary based on the specific product or service purchased or otherwise received. When determining the type and extent of control to be exercised over qualified suppliers, manufacturers should use an appropriate mix of evaluations, which can include audits and acceptance activities, to ensure that products and services conform to established specifications. Factors such as the tobacco product manufacturer's knowledge or control of the supplier's manufacturing practices, the supplier's history of providing acceptable products or services, history or trends of delivering products or services that do not meet specifications, and the impact of the product or service on the finished or bulk tobacco product meeting its established specifications, can inform the type and extent of control needed for a particular supplied product or service. For example, if a tobacco product manufacturer determines that a component supplier has a history of providing acceptable product that meets established specifications, it may determine that a CoA is an adequate control. However, if the tobacco product manufacturer observes a trend that a supplier has been providing nonconforming products that have been rejected and returned, it may determine that increased audits or incoming product acceptance activities such as testing may be needed to comply with these proposed requirements. FDA has observed on inspections that manufacturers may implement more rigorous control over those suppliers that are determined to have a ''critical'' impact on product specifications and controls (Ref. 97).

Proposed § 1120.62(b)(3) would require the qualification procedures to include developing a list of qualified suppliers and their product(s) or service(s) and updating this information periodically. This list of qualified suppliers is intended to help provide assurance to the manufacturer and FDA that each supplier has been evaluated and selected based on its ability to meet established requirements.

Proposed § 1120.62(b)(4) would require that, as part of the qualification procedures, finished and bulk tobacco product manufacturers monitor qualified suppliers to ensure they meet specified requirements and perform reevaluation as needed. This requirement could be met by periodic testing or sampling, or through periodic reevaluation of the types of information considered for initial evaluation and selection of a supplier (*e.g.,* records of nonconforming product, onsite audits, independent test results) under proposed § 1120.62(b)(1). Thus, the same kinds of information or records could be used for both initial qualification and ongoing monitoring of suppliers. For example, a manufacturer may use records of a supplier's performance (*e.g.,* records showing that a product meets established specifications) to initially qualify suppliers as well as to monitor their continued ability to meet specified requirements and determine whether any adjustments to the type and extent of control over qualified suppliers are necessary (see proposed § 1120.62(b)(2)). A manufacturer may determine that a supplier with a history of deficient auditing results or that repeatedly fails to meet established requirements should no longer be a qualified supplier.

FDA notes that this proposed rule would allow for different approaches to monitoring suppliers. While some suppliers might warrant onsite visits depending on the products at issue, some products could be monitored through acceptance activities. For example, if a supplier supplies a manufacturer with labels bearing the required warnings for its finished tobacco product and the historical rejection rate of the labels at receipt is 1 percent, but that rate has recently risen to 25 percent, the manufacturer may consider that supplier no longer qualified. Given that manufacturers are required to establish and maintain records of acceptance activities under proposed § 1120.64(e), reviewing trend lines across these activities would be an acceptable way to comply with this provision.

Proposed § 1120.62(c) would require finished and bulk tobacco product manufacturers to maintain records of all activities conducted under proposed § 1120.62. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

The records described in this proposed provision would include all types of purchasing records. Purchasing records are those records associated with any supplier contract, the established specifications for the product or service being provided, and any activities undertaken to qualify, requalify, and monitor suppliers. Purchasing records contain information on the specifications or requirements for a specific product or service. They could include a purchasing contract between a manufacturer and supplier, documents and records that set forth the quality requirements (*i.e.,* procedures and controls) that the supplier must comply with, documents and records that reflect the activities that the manufacturer uses to control and monitor the supplier (*e.g.,* audits), and documents and records provided by the supplier that indicate the established specifications for the product or service (*e.g.,* certificate of analysis (CoA), drawings, specifications sheets, catalogue numbers, engineering change order). Some types of purchasing records also may demonstrate compliance with other provisions of this proposed rule. For example, a CoA that documents the specified requirements for filters purchased from a supplier may constitute a purchasing record for purposes of this section, but it could also be used as an acceptance activity record to verify that a received batch of filters meets established specifications. Similarly, a finished tobacco product manufacturer using a contract pest control service to comply with the proposed animal and pest control requirement in § 1120.34(e) would be required to maintain the invoice documenting purchase of this service to satisfy the recordkeeping requirements under proposed § 1120.62(c) as well as the recordkeeping requirements under proposed § 1120.34(f).

Proposed § 1120.62(c) would also require that records maintained under this section include a written agreement (*e.g.,* purchase order, contractual agreement) that the supplier will notify the manufacturer of any change in the product or service so that the manufacturer can determine whether the change may affect the specifications of the finished or bulk tobacco product established in accordance with § 1120.44(a)(1). This provision is necessary to ensure that a supplier does not make any changes to the product or service without the knowledge of the finished or bulk tobacco product manufacturer that would result in a change to a finished or bulk tobacco product's specifications, rendering it a nonconforming product.

If a tobacco product manufacturer conducts audits to address the supplier qualification requirements at proposed § 1120.62(b), FDA, as a matter of policy, generally would not request to review or copy such audit records during routine inspections. Instead, FDA would consider a written certification by the manufacturer's management with executive responsibility stating that the audits have been performed and documented, the dates on which they were performed, and that any action taken in response to the audit results has been completed, as sufficient to meet the recordkeeping requirement under proposed § 1120.62(c). Nevertheless, this provision would not limit the Agency's ability to request for review or copy any procedures created to meet the requirement at proposed § 1120.62(b).

A tobacco product manufacturer could contract out certain activities required under proposed part 1120. To ensure purchased or otherwise received products or services conform to specified requirements, each tobacco product manufacturer would need to establish and maintain procedures to ensure that purchasing is carried out subject to adequate controls, including the evaluation and selection of suppliers, and the clear and unambiguous specification of requirements for such suppliers. In addition, the manufacturer would be required to have acceptance activities in accordance with proposed § 1120.64. These controls would help ensure that only suppliers that meet the specified requirements are used.

The finished or bulk tobacco product manufacturer would have the ultimate responsibility for ensuring that all applicable requirements under proposed part 1120 are met. For example, if a finished or bulk tobacco product manufacturer outsources laboratory testing services performed as part of an acceptance activity to a contractor, the manufacturer would be required to use purchasing controls to help ensure that the contract laboratory's procedures, processes, and records comply with the proposed laboratory controls requirements. The finished or bulk tobacco product manufacturer would be responsible if the contract laboratory does not adequately implement laboratory control processes. Additionally, the finished or bulk tobacco product manufacturer would be responsible for ensuring it receives all the documents and records needed to comply with proposed § 1120.122, including all relevant metadata. A supplier (including a contractor or consultant) would be directly responsible for complying with part 1120 to the extent that it is a finished or bulk tobacco product manufacturer under this proposed rule. For example, if a finished tobacco product manufacturer sends ENDS products to a contract packager to package and label the products for consumer use, the finished tobacco product manufacturer would be required to use purchasing controls to help ensure that the contract packager's packaging and labeling activities meet specified requirements; additionally, the contract packager would be covered under the proposed rule as a finished tobacco product manufacturer and would be directly responsible for the packaging and labeling requirements under the proposed rule (see the discussion of proposed subpart F in section IV.F).

The proposed regulation is intended to allow flexibility in the way finished and bulk tobacco product manufacturers ensure the acceptability of products and services. Under the proposed purchasing control requirements, manufacturers would be required to establish and maintain procedures that clearly define the type and extent of control they intend to apply to suppliers and their products and services. A finished or bulk tobacco product manufacturer may choose to provide greater in-house controls such as additional acceptance activities (see discussion of proposed § 1120.64 in section IV.F.2) to ensure that products and services meet specified requirements, or the manufacturer may require that the supplier adopt measures necessary to ensure acceptability, as appropriate, for example, batch testing. FDA believes that a mix of purchasing controls and in-house manufacturing controls will generally be necessary to ensure acceptability of received products and services. A manufacturer could review and approve the supplier's procedures or perform supplier audits to assess the supplier's continued capability to provide acceptable product. The manufacturer could also review historical data, monitor and look for trends in data such as acceptance and nonconforming product records, and perform inspection and testing of received products.

FDA has observed that tobacco product manufacturers use a variety of different purchasing controls to ensure that received products and services conform to established specifications. For example, a manufacturer may use different purchasing controls based on the degree of impact that the supplied product or service may have on the

finished or bulk tobacco product. A manufacturer may determine that a supplier of liquid nicotine would need to provide a certificate of analysis of the nicotine concentration for each batch, undergo a yearly audit, and send every fifth batch for an independent laboratory analysis to confirm a nonconformance rate of less than 1 percent. In contrast, the manufacturer may determine that a supplier of outer packaging for shipping (that does not come into contact with the tobacco product) only needs to be initially qualified and to maintain production records for review by the manufacturer as requested. In addition, these proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001.

The proposed purchasing controls requirements would help assure that the public health is protected by ensuring that suppliers are capable of providing products and services that conform to established specifications and other specified requirements set by the manufacturer. A change in a received product may impact one or more of the established specifications of the finished or bulk tobacco product, rendering it nonconforming. For example, a menthol supplier may change its menthol formulation by using a different chemical compound, such as L-menthol instead of D-menthol stereoisomer. This change in formulation may affect the specification for this ingredient and cause the finished tobacco product not to meet the specifications for menthol established in the MMR. This change is formulation may also impact public health as the change from D-menthol to L-menthol may promote smoking initiation and nicotine addiction (Ref. 98).

A change in service also may impact an established specification. For example, if a contract laboratory changes the sampling plan for product acceptance, the test results may no longer be representative of the product, which may result in a nonconforming product. Use of components or parts, ingredients, additives, and materials that do not meet specifications may result in the manufacture of a nonconforming tobacco product. In addition, use of an unqualified laboratory to perform testing and sampling may result in a failure to conduct adequate product acceptance activities and in the manufacture of a nonconforming tobacco product.

The proposed purchasing controls requirements would also help assure that tobacco products are in compliance with chapter IX of the FD&C Act. For example, purchasing controls would help ensure that products meet relevant requirements under sections 905 and 910 of the FD&C Act and that such products are not adulterated under section 902(6) or misbranded under section 903(a)(6) of the FD&C Act. The proposed requirements would enable the tobacco product manufacturer to be aware of any change to supplied products so that it may determine whether the change may affect the established specifications of the finished or bulk tobacco product in the MMR. A change in an established tobacco product specification can result in a modification and the creation of a new tobacco product under section 910(a)(1)(B) of the FD&C Act for which premarket review is required. For example, a change in the denier per filament specification of the acetate tow material of a cigarette filter would change the filter's pressure drop, rendering it a new tobacco product (Ref. 99). Therefore, this section would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to their tobacco products that may render the products adulterated under section 902(6) or misbranded under section 903(a)(6) of the FD&C Act. In addition, if a tobacco product standard establishes requirements respecting a component of a tobacco product, the proposed purchasing controls requirement would help a finished tobacco product manufacturer that obtains such component from a supplier to ensure that the purchased or received component conforms to the standard. Likewise, if a tobacco product standard establishes requirements for testing of a tobacco product and the testing is performed by a contract laboratory, the proposed requirement would help ensure that the purchased or received service results in a product that conforms to the tobacco product standard.

The proposed purchasing controls requirements would also help ensure that tobacco products are not adulterated under section 902 of the FD&C Act by ensuring that purchased or received products are not contaminated or held under insanitary conditions. For example, a bulk manufacturer may require through purchasing controls that leaf producers follow a Good Agricultural Practice program, including the use of approved pesticides. This would help ensure that purchased leaf tobacco is not treated with unapproved pesticides that may contain ''any added poisonous or added deleterious substance that may render the product injurious to health'' and, therefore, adulterated under section 902(1) of the FD&C Act.

2. Acceptance Activities

Proposed § 1120.64(a) would require tobacco product manufacturers to establish and maintain procedures for acceptance activities, including acceptance criteria. Acceptance activities can be used throughout the production process—incoming, during the receipt of incoming materials; in-process, during the manufacturing process; and final, prior to the release of the finished or bulk product for distribution. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001.

Acceptance activities could include inspections, tests, evaluations, and other verification activities. Inspections could include visual inspection of incoming, finished, or bulk tobacco products (Refs. 100 and 101). Testing could include laboratory testing, such as testing the resistance to draw of a cigarette (Ref. 102). Other verification activities could include, for example, review of a supplier's CoA to ensure that an ingredient meets its specification for purity (*e.g.,* Ref. 103), or use of worksheets or programs to determine that the correct amount or weight of materials, ingredients, and additives has been used. In addition, tobacco product acceptance activities could include use of a validated production process with appropriate continued process verification under proposed § 1120.66(b).

Although a manufacturer could rely on the review of purchasing records during incoming acceptance such as a CoA, there may be circumstances where testing or inspection may be necessary for accepting incoming product. For example, if a manufacturer determines that a supplier's product is close to the outer parameters of acceptability, the manufacturer could establish a testing requirement to audit the supplier under § 1120.62(b)(2) to confirm the information that is supplied in the CoA. Manufacturers would have the flexibility to choose which acceptance activity method(s) is most suitable to their needs, products, and manufacturing process.

Proposed § 1120.64(a) also would require that procedures for all acceptance activities include acceptance criteria. Acceptance criteria could be expressed as values, ranges, or tolerances or may include criteria such as appearance, color, or specific gravity (*e.g.,* Ref. 104). For example, under these proposed requirements, an e-liquid manufacturer who uses liquid

nicotine to make e-liquids could perform laboratory testing as an acceptance activity to verify that a specification for the concentration of incoming liquid nicotine is met. If the manufacturer's MMR establishes the specification at 90 percent nicotine and the specification's acceptance criteria is designated with a tolerance of ±0.40 percent, the laboratory testing results would need to show that the concentration of nicotine is between 89.6 percent and 90.4 percent to meet the established specification. Under the proposed requirements, if the incoming liquid nicotine has a nicotine concentration of less than 89.6 percent or greater than 90.4 percent, the manufacturer would need to treat the incoming liquid nicotine as a nonconforming product in accordance with proposed § 1120.74.

In addition, acceptance activities that involve sampling would be required to use representative sampling under proposed § 1120.72. Representative samples are frequently used to determine whether a batch of tobacco product meets specifications. While FDA is aware that some tobacco product manufacturers use sampling plans for acceptance activities, the Agency believes that this requirement is needed to ensure that all manufacturers who perform sampling in their acceptance activities use representative samples to demonstrate that a batch meets established specifications. CORESTA has also developed recommended methods for sampling plans for the preparation of samples of different types of tobacco products, such as cigarettes, smokeless tobacco, fine-cut tobacco, and cigars (Refs. 105, 107, 108).

Proposed § 1120.64(b)(1) would require that the acceptance activity procedures address acceptance activities for all incoming products to ensure that any specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met and that such products are not contaminated or deteriorated. The term ''incoming products'' would include not only incoming tobacco products, but also any incoming equipment that is used in the manufacturing of tobacco products, such as cigarette makers, as well as any other materials that may be used, such as cleaning agents that may be used to clean the tobacco contacting equipment and may leave residues that might contaminate the tobacco. Some tobacco product manufacturers already use acceptance activities to verify that incoming products meet established specifications. For example, organic solvents such as toluene often are used for the printing of cigarette packages. A tobacco product manufacturer could evaluate a CoA for incoming cigarette packages that indicates an upper limit for the acceptance criteria of each organic solvent. The tobacco product manufacturer could review the analysis results in the CoA showing the actual measurement of the organic solvent to determine whether these incoming materials are acceptable for use in manufacturing (*e.g.,* Ref. 109). A tobacco product manufacturer could also conduct its own laboratory testing of incoming material to determine that it meets established specifications (*e.g.,* Ref. 110).

Proposed § 1120.64(b)(1) also states that each accepted incoming tobacco product would need to be designated by a unique identifier, which must be maintained throughout manufacturing and documented in accordance with § 1120.70(b)(5). Incoming acceptance would apply to all incoming products, but the unique identifier requirement would be limited to those products that meet the definition of a tobacco product. Once the tobacco product manufacturer accepts an incoming tobacco product for use in the manufacturing process, a unique identifier would be assigned. A unique identifier is information, such as a code or number that is maintained for each accepted incoming tobacco product, that would enable the tobacco product manufacturer and FDA to identify the supplier and unique shipment (*e.g.,* purchase order) of the incoming tobacco product. The proposed unique identifier requirement would establish traceability for all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product and would aid in investigations related to tobacco product complaints, CAPAs, and nonconforming products. For example, during an investigation of a nonconforming product, the unique identifiers of all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product would enable the manufacturer to determine the scope and cause of the nonconformance. If a nonconformity is attributed to a nonconforming component or part, ingredient, additive, or material, the manufacturer could take appropriate corrective action with respect to any other affected finished or bulk tobacco product that uses the affected tobacco product. For an incoming finished or bulk tobacco product, the unique identifier would be required to include, or be traceable to, the manufacturing code on the packaging or label of the incoming finished or bulk tobacco product. This could be a separate unique identifier or it could incorporate the manufacturing code of the incoming finished or bulk tobacco product. This requirement would be important for tobacco product manufacturers who perform only packaging and labeling, including repackaging and relabeling, as the unique identifier would establish traceability to the specific batch of the incoming finished or bulk tobacco product.

FDA is not proposing to prescribe the format or mechanism (*e.g.,* affixing a batch or control number to the immediate container or product label) of the unique identifier requirement. Rather, manufacturers would have the flexibility to determine the method that they would use to track and identify the received and accepted incoming tobacco products that are used in the manufacture of finished and bulk tobacco products. On inspections, FDA has observed manufacturers using various means of implementing unique identifiers, including programmable and scannable bar codes and tags affixed to the immediate container.

FDA is proposing that the unique identifier for each accepted incoming component or part, ingredient, additive, and material used in the manufacture of finished and bulk tobacco products would need to be documented in the production record in accordance with proposed § 1120.70(b)(5). Although not required by this proposed rule, as components and parts undergo further manufacturing and become a new component or part, ingredient, additive, or material, a manufacturer may choose to assign a new unique identifier to the combined product, subassembly, or batch of tobacco product. The new unique identifier would establish more accurate traceability to account for all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product and would aid in investigations related to tobacco product complaints, CAPAs, and nonconforming products. However, any original unique identifier would need to be maintained in the production record, even if a subsequent unique identifier is assigned to the product after further manufacturing. For example, if an e-liquid manufacturer assigns a unique identifier for banana and vanilla flavor ingredients under § 1120.64(b)(1) and further processes these ingredients to make a batch of banana crème flavor, it may assign a new identifier for the new flavor. If this approach is used, traceability to the unique identifiers of the new, as well as the original, individual components and parts, ingredients, additives, and materials would need to be maintained in

accordance with proposed § 1120.70(b)(5).

This provision also would require that the results of incoming acceptance activities be reviewed and approved to ensure that the incoming tobacco product specifications established under proposed § 1120.44 or through purchasing controls under proposed § 1120.62 are met and that the product is not contaminated or deteriorated. Therefore, prior to using incoming product in the manufacturing process, a designated qualified individual would be required to review the results of the incoming tobacco product acceptance activities, determine that the specifications established in the MMR and through purchasing controls are met and that the product is not contaminated or deteriorated, and approve the release of the product for manufacturing. The acceptance status of the released tobacco product would be maintained under proposed § 1120.64(d). FDA has observed on inspections that the number of personnel or the complexity of the manufacturing process may determine whether the review and approval of incoming acceptance activities is performed by the individual who conducted the acceptance activity or a designated quality assurance employee who reviews and approves acceptance activity results conducted by others. The proposed rule would afford the manufacturer flexibility to determine how it would perform this activity, as long as it occurs prior to the release of incoming product for manufacturing.

Proposed § 1120.64(b)(2) would require that acceptance activities procedures address the testing and acceptance of raw tobacco to ensure that raw tobacco from suppliers (internal and external to the organization) complies with established specifications for pesticide chemical residue(s). The specifications for pesticide chemical residue(s) would need to be established by the manufacturer and comply with any applicable tolerance(s) established under Federal law.[5] FDA considers raw tobacco to include tobacco leaf and tobacco cut rag that is received from importers, wholesalers, and distributors.

Manufacturers would be required to comply with this requirement for all tobacco products containing raw tobacco. A tobacco product manufacturer could comply with this proposed requirement by performing its own testing or accepting a CoA from the supplier of the raw tobacco showing that relevant specifications for pesticide chemical residue(s) are met (*e.g.,* Refs. 111 and 112). On inspections, FDA has observed that several tobacco product manufacturers have established specifications for pesticide chemical residues for raw tobacco, taking into account recommendations in CORESTA's Guide No. 1—The Concept and Implementation of CPA (crop protection agent) Guidance Residue Levels (Ref. 86), and voluntary U.S. Department of Agriculture pesticide residue standards at 7 CFR 29.427.

Proposed § 1120.64(b)(3) would require that all incoming tobacco products, *i.e.,* components or parts, ingredients, additives, and materials, be evaluated during incoming acceptance activities to ensure that they are not contaminated or deteriorated. FDA is aware that tobacco product manufacturers have considered and used different methods to evaluate products for physical and some biological contamination including metal detectors, x-rays, and optical sorters (*e.g.,* Refs. 113 and 114). Tobacco product manufacturers could establish procedures to visually inspect incoming product for contamination or sources of potential contamination (*e.g.,* Refs. 115 and 116). Any of these methods could be suitable for compliance with this proposed section, depending on the product being inspected. Deterioration of components or parts, ingredients, additives, and materials could result in nonconforming product or otherwise render the product adulterated or misbranded. Examples of possible deterioration include discoloration, spotting, and staining of components (such as packaging, labels, filters) or flavors or additives that have passed their expiration date.

Proposed § 1120.64(c) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for in process and/or final acceptance activities to ensure that each finished or bulk tobacco product meets the specifications established under proposed § 1120.44. Tobacco product manufacturers could comply with proposed § 1120.64(c) in process or after manufacturing a finished or bulk tobacco product. A manufacturer could comply with this provision by performing batch testing on finished or bulk product. Any acceptance activities that involve sampling would be required to comply with proposed § 1120.72. On inspections, FDA has observed that tobacco product manufacturers may perform acceptance activities at discrete points in the production process or use a stage-gate approach to accept tobacco product and release it to the next stage of processing (*e.g.,* Ref. 117). For example, acceptance activities could be performed on tobacco blends after primary processing, on smokeless tobacco blends after fermentation, and on cigarettes or smokeless tobacco product after making. Acceptance activities could also be performed after the tobacco product is packaged; for example, testing the finished tobacco product to ensure that it meets established specifications (*e.g.,* Ref. 118) and inspecting the product packaging to determine it meets all packaging and labeling requirements.

This provision also would require that the results of in-process and final acceptance activities be reviewed and approved to ensure that the finished and bulk tobacco product specifications established under § 1120.44 are met. Therefore, a designated qualified individual would need to review the results of the tobacco product acceptance activities to determine that the specifications established in the MMR are met, and approve the release of the finished or bulk tobacco product for distribution. As discussed previously regarding proposed § 1120.64, the proposed rule would afford the manufacturer flexibility to determine how it would perform this activity, as long as it occurs prior to distribution.

Proposed § 1120.64(d) would require tobacco product manufacturers to identify, by suitable means, the acceptance status of a tobacco product throughout the different stages of the manufacturing process, indicating whether the tobacco product is a conforming or nonconforming tobacco product. The identification of the acceptance status would need to be maintained from receipt of incoming products throughout manufacturing and until the finished or bulk tobacco product passes required acceptance activities and is released for distribution. FDA considers ''suitable means'' to mean that the acceptance status of a tobacco product can be readily determined. For example, tobacco product manufacturers could use various methods to identify the acceptance status of tobacco products, including scannable barcodes, labels, markings and other methods (*e.g.,* Refs. 119 and 120). This requirement is intended to ensure that manufacturers can effectively identify the acceptance status of tobacco products and prevent mixups.

[5] Under 907(a)(1)(B) of the FD&C Act, a tobacco product manufacturer cannot use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco. As of publication of this proposed rule, such a tolerance level has not been established by Federal statute or regulation.

This provision seeks to ensure that the acceptance status of all tobacco products, including incoming tobacco products, in-process tobacco products, and finished and bulk tobacco products is properly identified throughout manufacturing to ensure that only tobacco products that pass required acceptance activities are incorporated into the finished or bulk tobacco product and ultimately released for distribution. This requirement is intended to prevent nonconforming tobacco product from being used in the manufacture of a finished or bulk tobacco product. For example, if a smokeless tobacco blend does not conform to a fermentation specification during a tobacco product acceptance activity, its nonconforming acceptance status would need to be identified so that it would not be used in the manufacture of a finished smokeless tobacco product.

Proposed § 1120.64(e) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. This provision would require records to include the date and time, individual performing the activity, type of activity performed, acceptance criteria, any information that demonstrates the requirement was met, equipment used if applicable, and any data or calculations necessary to reconstruct the results. This provision is necessary to help ensure that acceptance activities are performed according to established procedures and that the tobacco product meets the specifications established in proposed § 1120.44. The date and time when the acceptance activities were conducted and the name of the individual who performed the activities could help manufacturers and FDA identify the scope of any nonconformity.

The proposed acceptance activities requirements would help assure that the public health is protected. Tobacco product specifications could impact the toxicity and addictiveness of the product, and acceptance activities would help ensure that tobacco products do not exceed established specifications that affect these parameters. For example, if a tobacco product manufacturer establishes a nicotine concentration level for an ENDS product, acceptance activities would help ensure that the tobacco product meets that specification. This would be important because a finished ENDS that contains a nicotine concentration higher than the established specification could be more addictive (Refs. 4 and 5).

In addition, the physical design specifications of a tobacco product interact with its chemical composition to influence its function and effect on consumers, which can impact the toxicity and addictiveness of the product (Ref. 6). For example, the design of a cigarette filter's ventilation impacts the level of nicotine in the cigarette's smoke (Ref. 96). If a cigarette's filter deviates from its established ventilation design specification, the amount of nicotine delivered to the user may be affected, which can increase addictiveness. A tobacco product's operating and design specifications and features can affect the toxicity and addictiveness of the product. For example, a variable voltage ENDS product can enable a user to control the power input. The electrical power input—which is proportional to the square of the voltage and inversely proportional to the heater resistance—influences the temperature at which the aerosol is produced, which may influence nicotine and other toxicant emissions (Ref. 121). Acceptance activities would verify that the tobacco product conforms to its established design specification and, therefore, help to minimize additional harm associated with nonconforming products.

The proposed acceptance activities requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Acceptance activities would help tobacco product manufacturers to verify, and enable FDA to confirm, that finished and bulk tobacco products conform to established specifications. These provisions would help ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. The acceptance activities requirements also would help ensure that the packaging, labeling, and labels of finished tobacco products comply with applicable statutory and regulatory requirements. For example, by ensuring that correct packaging, labeling, and labels are used with each product, the acceptance activities and associated records would help ensure that labeling does not contain false or misleading statements, that packages and labels bear required health warnings or statements, and that the labeling or labels do not contain unauthorized modified risk claims. Additionally, the acceptance activities requirements and associated records would help ensure that a product is compliant with any product standards established by FDA under section 907 of the FD&C Act. For example, under section 907, FDA could require a reduction or elimination of an additive or constituent. The acceptance activity records would help enable FDA to verify that the amount of the additive or constituent in the manufacturers' products meets the product standard.

The proposed requirements also would help ensure that tobacco products do not contain a contaminant or hazard that may cause the product to be adulterated under section 902(1)–(3) of the FD&C Act. For example, visual inspection of incoming tobacco leaf for mold or NTRM (including glass or metal fragments) or use of metal detectors, x-rays, optical sorters, and other methods would help minimize the likelihood that tobacco products contain such substances.

3. Production Processes and Controls

Proposed § 1120.66(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for their production processes, including process controls, to ensure that tobacco products conform to requirements established in the MMR in accordance with proposed § 1120.44. Production processes include the methods, activities, or steps that a tobacco product manufacturer uses to manufacture a tobacco product. Production processes may include primary processing such as blending, casing, and cutting tobacco; fermenting tobacco; mixing flavors and liquid nicotine; and assembling components or parts.

Under proposed § 1120.66(a)(1), production process procedures would be required to address production process specifications with relevant acceptance criteria. For example, a manufacturer could establish production specifications for moisture with relevant acceptance criteria at different points in the production process to ensure that the tobacco product moisture specification is met at the point of each acceptance activity. Similarly, a manufacturer could establish time, temperature, and humidity production process specifications with relevant acceptance criteria to ensure that the tobacco product pH specification is met.

Proposed § 1120.66(a)(2) would also require that the production process procedures include relevant process controls such as monitoring and acceptance activities (inspection, testing, evaluation, and other verification activities). For example, if a

manufacturer established production process specifications with acceptance criteria, such as time, temperature, and humidity, the manufacturer would be required to implement relevant process controls such as monitoring or testing tobacco product to verify that such production process specifications are met. Under proposed § 1120.66(a)(2), such process controls would be included in the production process procedures. The proposed requirements are intended to provide tobacco product manufacturers with the flexibility to establish the production process procedures that are appropriate for their particular manufacturing operations and type of tobacco products to ensure that manufactured tobacco products conform to the requirements established in the MMR in accordance with proposed § 1120.44.

Proposed § 1120.66(a)(1) and (2) are intended to help ensure that the production process is controlled so that tobacco products meet their product specifications at the appropriate acceptance activity stage. For example, the fermentation of smokeless tobacco must occur under specific environmental conditions to assure that at the end of fermentation desired specifications, such as pH and oven volatiles are met. The production process procedures required by this proposed provision would, therefore, specify that fermentation occur in an environmentally-controlled room. The manufacturer would need to establish time, temperature, and humidity ranges for the room to ensure that the room is maintained within the environmental ranges required to meet product specifications. In this example, the production process specifications would be the upper and lower temperature and humidity limits for specified durations. The manufacturer would also use relevant process controls such as monitoring activities to confirm that the process occurred within the required time, temperature, and humidity ranges and to alert staff if these conditions are not met, for example, if the room temperature is drifting towards a temperature that does not meet the established production process specification.

Proposed § 1120.66(a)(3) would require that the production process procedures include a requirement for investigating any deviations from the production process specifications and established acceptance criteria, or from relevant process controls, to determine if the deviation results in a nonconforming product. Process deviations can be identified from process and product sources, such as process monitoring, acceptance activities, production records, and records of nonconforming products. For example, if the fermentation of a tobacco blend deviates from established production processes and controls for fermentation, such as maintaining temperature and humidity through specified turn cycles necessary to meet a pH specification, the tobacco product manufacturer would be required to perform an investigation to determine if the deviation results in a nonconforming product. Proposed § 1120.66(a)(3) would also require that the manufacturer document the disposition of any product affected by the deviation. A product manufactured under conditions that deviate from the process specifications could be released for further processing or distribution if the investigation determines that the product conforms to product specifications, for example, if data from process validation activities demonstrates that product produced within those process specifications still conforms to product specifications. Product found to be nonconforming would need to be handled in accordance with proposed § 1120.74.

If a manufacturer finds that its originally established process specifications are difficult to maintain (*i.e.,* result in many process deviations), the manufacturer may decide to use a wider range of process specifications for future production where it is supported by the original process validation activities, rather than investigating each time a product is produced outside the narrower range. In such a case, the proposed rule would require that the updated process specifications be documented in the MMR in accordance with the procedures established under § 1120.44. If the manufacturer decides to adopt new ranges beyond the originally validated process specifications, the manufacturer would need to evaluate the change under proposed § 1120.66(a)(4) and revalidate the process, where appropriate.

Proposed § 1120.66(a)(4) would require that the production process procedures include a requirement for evaluating all changes to production processes, including process controls, to determine their impact on the tobacco product specifications in the MMR. If any production process changes result in a change to the tobacco product specifications, the proposed rule would require that the manufacturer ensure that procedures applicable to the changes in tobacco product specifications are followed in accordance with §§ 1120.42 and 1120.44 and update the tobacco product specifications in the MMR as needed. This requirement is intended to ensure that the manufacturer identifies changes to a production process that may affect a tobacco product specification and, therefore, lead to a nonconforming product. For example, if a manufacturer uses a 3-turn fermentation process to manufacture a smokeless tobacco product with an established pH specification, and the tobacco product manufacturer changes the fermentation process to a 2-turn process, under this proposed provision, the manufacturer would need to evaluate the production process change to determine if it results in a change to the pH (or any other specifications) of the smokeless tobacco product. If it does, then the manufacturer could decide against making the process change or could change the tobacco product specifications in accordance with proposed §§ 1120.42 and 1120.44.

Proposed § 1120.66(a)(4) would also require that any changes to validated processes be revalidated before implementation, where appropriate. For example, if a tobacco product manufacturer makes a change to the validated forming and drying process for reconstituted leaf tobacco by adjusting the thickness and pressure of the size press, these changes would need to be evaluated and revalidated, where appropriate, before being implemented.

In addition to the requirements in proposed § 1120.66(a), proposed § 1120.66(b) would require that the production process procedures include requirements for process validation, if applicable. Specifically, if the results of a process cannot be fully verified (including any automated processes), this provision would require finished and bulk tobacco product manufacturers to validate the process to demonstrate that the process will produce a tobacco product that conforms to the tobacco product specifications established under § 1120.44(a)(1). The results of a process cannot be fully verified, for example, where the manufacturer cannot demonstrate that the tobacco product meets established specifications through acceptance activities using representative samples (*e.g.,* automated cigarettes manufactured with millions or tens of millions of cigarettes in a batch, because the size of the batch is too large) or where acceptance activities cannot fully determine whether the product meets established specifications (*e.g.,* laser welding of an ENDS atomizer to a tolerance of ±0.0002 inches)). Although this provision would not require processes to be validated where the results can be fully verified, the

Agency encourages manufacturers to validate all processes.

Process validation includes activities to establish scientific evidence that a process is capable of consistently producing product that conforms to established specifications. FDA is aware that some tobacco product manufacturers use validation master plans to validate the processes and equipment for the manufacturing and packaging of tobacco products; these plans cover the criteria for review and approval of the processes, specific methods and procedures to qualify the process, methods for continued process verification through monitoring and measurement of the processes, and revalidation.

This proposal would require process validation to use appropriate objective measures and valid scientific tools and analyses to maintain the process in a state of control. Examples of valid scientific tools and analyses used in process validation would include a capability study to measure the ability of the process to consistently meet specifications, challenge tests to demonstrate where nonconformities are due to variation and off-target processes under worst-case conditions, and acceptance sampling plans to determine the number of samples to be tested to provide a gross check for defect rate increase with respect to a predetermined acceptable quality level (*e.g.,* Ref. 122). Acceptance sampling can be based on standards (*e.g.,* ISO 28590:2017, ISO 3951:2013, ANSI Z1.4, ANSI Z1.9) (Refs. 123–126).

Proposed § 1120.66(b)(1) would require finished and bulk tobacco product manufacturers, as part of process validation, to design a production process for manufacturing a tobacco product. The process design would need to address the capability and functionality of the production process. The process design also would establish a strategy for process control to develop operational limits and monitoring of the production process that should take into account the building, facility, and equipment and possible sources of variability posed by personnel and environmental conditions. This provision is intended to help ensure that products conform to established specifications.

For example, a cigarette maker can operate at speeds up to 20,000 cigarettes per minute and manufacture cigarettes to specifications of weight, length, and diameter. In this case, proposed § 1120.66(b)(1) would require a manufacturer to address the capability and functionality of its production process at various operational speeds and establish a strategy for process control. The tobacco product manufacturer may determine that the cigarette maker operates at an optimal speed of 16,000 cigarettes per minute and the process control could consist of samples being taken every 30 minutes to monitor the production process. However, if the maker operates at its maximum 20,000 cigarettes per minute speed, a process control could consist of samples being taken more frequently (*e.g.,* every 15 minutes) to assure that the tobacco product remains conforming at the increased production speed.

Alternatively, in a case where the product attribute is not readily measurable due to limitations of sampling or detectability, operational limits and in-process monitoring parameters could be established for process control. For example, a manufacturer may establish process specifications for manufacturing cigarette filter rods. The manufacturer would have to validate the process used by the automated filter rod maker to ensure that filters meet product specifications. For this process, the manufacturer could establish a target specification for parameters such as the pressure drop. The lower specification and upper specification limits or tolerances would also need to be developed around the target specification. The manufacturer would then be required to determine lower and upper process control limits for parameters such as the speed of cellulose acetate fiber that is fed into the rod maker. These process control limits would be at values between the target and lower and upper specification limits. Based on the results obtained by a predetermined sampling plan, the values would be used to adjust the machine to ensure that filters are manufactured in accordance with the product specifications.

For any required process validation activities, proposed § 1120.66(b)(2)(i) would require finished and bulk tobacco product manufacturers to perform process qualification to determine if the process is capable of reproducible manufacturing. Manufacturers would need to demonstrate that the design of the facility is appropriate and qualify the equipment to confirm that it is suitable for its intended purposes and will perform properly. This could involve qualifying that the equipment is appropriate for its specific use, verifying that equipment is built and installed in conformance with its design specifications, and verifying that equipment operates properly in all anticipated operating ranges. Proposed § 1120.66(b)(2)(ii) would require manufacturers to perform process performance qualification to confirm the process design and to demonstrate that the manufacturing process performs as expected in accordance with established criteria, which would need to be documented in a written protocol. This could involve utilizing the qualified equipment with trained personnel and production process procedures, including process controls, to confirm the process design and demonstrate that the commercial manufacturing process performs as expected.

Proposed § 1120.66(b)(3) would require finished and bulk tobacco product manufacturers to monitor the production process using data collected from records required under proposed part 1120 and valid scientific tools to detect variability and ensure that the process remains in a state of control. This proposed requirement is intended to help prevent process deviations. A manufacturer could accomplish this by monitoring for undesired process variability and determining the appropriate actions to correct, anticipate, and prevent problems. Relevant process and product data must be collected from records covered under proposed part 1120, and would include data regarding acceptance activities (proposed § 1120.64) and reviews of nonconforming product (proposed § 1120.74).

Valid scientific tools can include statistical process control techniques, control charts, recognized standards such as American Society for Testing and Materials (ASTM) E2281–03 ''Standard Practice for Process and Measurement Capability Indices'' and ASTM E2709–09 ''Standard Practice for Demonstrating Capability to Comply with a Lot Acceptance Procedure'' (*e.g.,* Refs. 127–130). The collection and analysis of data and use of valid scientific tools can detect trends caused by process deviations.

If continued process verification under proposed § 1120.66(b)(3) reveals that the process is no longer operating in a state of control and requires a change to the existing validated production process, such as to its method, procedure, or process control, revalidation under proposed § 1120.66(a)(4) would be required.

Proposed § 1120.66(c) would require that the production process procedures include certain additional requirements, if applicable. Under proposed § 1120.66(c)(1), if a production process includes a manual method or process, the production process procedures would be required to describe the manual method or process in sufficient detail to ensure that the tobacco product

meets established specifications and include, if applicable, the criteria for workmanship using a standard or approved model sample. An actual or diagrammatic representation of a model sample could show the design and construction of a tobacco product. For example, a hand-rolled cigar could be represented by a model sample that defines the type and size of tobacco leaf to be used for the wrapper, the type and amount of filler tobacco to be used, the brand label to be applied, and the size/shape/length/diameter of the finished, rolled cigar. Similarly, a documented standard could establish specific length, gauge width, and shapes of certain types of standardized cigars (*e.g.,* Corona, Churchill, and Panetela) (Ref. 131).

Proposed § 1120.66(c)(2) would require that the production process procedures address the use and removal of manufacturing material if such material could reasonably be expected to contaminate a tobacco product or otherwise result in a nonconforming tobacco product. For example, if a tobacco product manufacturer uses a mold release agent for an injection molding process for smokeless tobacco containers, and that agent contains volatile solvents that can contaminate the tobacco product and be toxic to users, the production process procedures would need to address how to clean and remove the manufacturing material (*e.g.,* Refs. 132–134).

Proposed § 1120.66(d) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. These records could include drawings of the process validation process, a general outline of steps for process validation, or meeting agendas and notes regarding the validation process (*e.g.,* Refs. 135–137).

The proposed production processes and controls requirements would help assure that the public health is protected because they can prevent, monitor, and detect variability in the manufacturing process. Variability in the manufacturing process may result in the manufacture of tobacco product that does not conform to established specifications. For example, many tobacco product manufacturers establish moisture specifications for finished and bulk tobacco products. The regulation of moisture throughout the production process is important because of the influence of moisture on tobacco and other components and parts, their processing properties, and on the finished tobacco product itself (Ref. 138). Moisture also can affect the properties of tobacco and other components and parts (*e.g.,* paper, filters), such as the level of micro-organisms and mass, hardness, circumference, pressure drop, and filter ventilation (id.). In addition, the moisture content of a finished cigarette is one of the physical variables that can affect the level of total particulate matter and the chemical composition of particulate phase smoke, such as during the initial puffs (Ref. 139). Similarly, many tobacco product manufacturers establish a pH specification for smokeless tobacco products using production processes such as curing, fermentation, or pasteurization. An increase in pH can result in an increase in the speed of nicotine absorption, which is associated with the development of tolerance and physical dependence to nicotine (Ref. 19). Inadequate production processes and controls may also contribute to substantial variability in actual nicotine concentration as compared to labeled nicotine concentration in e-liquids intended to be used with ENDS (Ref. 1). This variability could be particularly problematic for users seeking to limit or cease tobacco product use. Therefore, these proposed provisions are needed to prevent the manufacture and distribution of nonconforming products that may have an adverse effect on public health.

In addition, the proposed requirements for production processes and controls would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If tobacco products are not consistently manufactured to conform to established specifications, new tobacco products and MRTPs may not conform to the specifications that are described in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and pre-existing tobacco products may not be manufactured consistent with their original characteristics. Relatedly, the proposed requirements would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to tobacco products that may render them new and adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act. Further, a finished or bulk tobacco product whose contents, such as nicotine concentration, are not consistent with its labels or labeling also may be deemed misbranded and subject to regulatory action.

4. Laboratory Controls

Proposed § 1120.68 establishes requirements for laboratory controls. Under proposed § 1120.68(a), finished and bulk tobacco product manufacturers would be required to demonstrate laboratory competence when using a laboratory (either in-house or contract laboratory) to conduct activities under proposed part 1120. Under proposed § 1120.68(b), finished and bulk tobacco product manufacturers would also be required to establish and maintain laboratory control procedures for any laboratory activities that are conducted under proposed part 1120. Laboratory activities conducted under proposed part 1120 may include, for example, those used for design and development activities, acceptance activities, and process controls, and for the calibration of testing, monitoring, and measuring equipment. The requirements under proposed § 1120.68(a) are intended to ensure that the facilities and personnel of in-house laboratories, as well as those of contract laboratories, are competent to perform the laboratory testing conducted under proposed part 1120. The requirements under proposed § 1120.68(b) establish the specific requirements that the laboratory control procedures would be required to address in order to ensure that the laboratory testing is adequately performed.

Proposed § 1120.68(a) would require finished and bulk tobacco product manufacturers, when using a laboratory (either in-house or contract) to conduct activities under proposed part 1120, to demonstrate the laboratory's competence to perform laboratory activities associated with the manufacture of finished and bulk tobacco products. This proposed requirement is intended to ensure that tobacco product manufacturers confirm that laboratories are technically competent and able to produce precise and accurate data to comply with proposed part 1120. While manufacturers would have the flexibility to determine how they would demonstrate a laboratory's competency, they would be required to have appropriate documentation. Tobacco product manufacturers could utilize various means to show their laboratory's competency to carry out its activities such as a standard accreditation, such as ISO 17025:2005 (Ref. 140), or otherwise documenting a laboratory QMS (*i.e.,* standard operating procedures for test methods, equipment maintenance and calibration logs, quality control

sampling protocols, and personnel training).

Proposed § 1120.68(b) would require finished and bulk tobacco product manufacturers to establish and maintain laboratory control procedures for any laboratory activities that are conducted under proposed part 1120. The laboratory control procedure requirements in proposed § 1120.68(b)(1) through (3) are inter-related and intended to ensure that manufacturers utilize appropriate laboratory facilities and equipment, and that laboratory activities associated with the manufacture of tobacco products are performed with controls sufficient to ensure accurate and reliable results. For example, a manufacturer may use a laboratory to test pH levels of smokeless tobacco products to ensure that the pH levels meet the product specifications (Ref. 141). The laboratory control requirements in this section would help ensure that the data from such laboratory testing are accurate and precise, for example, by helping ensure that the laboratory uses properly calibrated pH meters, nonexpired pH check solutions, and a valid test method (Ref. 141).

If a tobacco product manufacturer contracts its laboratory activities to an outside entity, the manufacturer would remain responsible for complying with the proposed laboratory control requirements. However, we note that these proposed requirements would not apply to laboratory activities outside the scope of manufacturing activities. For example, the proposed requirements would not apply to testing for harmful and potentially harmful constituents performed solely to comply with section 904(a)(3) of the FD&C Act.

Proposed § 1120.68(b) would require the laboratory control procedures to include several specific laboratory control requirements. First, proposed § 1120.68(b)(1) would require the laboratory controls to include the use of scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose. A laboratory method can be scientifically valid if it is based on scientific data or results published in, for example, scientific journals, references, or text books.

Second, proposed § 1120.68(b)(2) would require laboratory controls to include the use of representative samples based on valid scientific rationale, in accordance with proposed § 1120.72. As further described in proposed § 1120.72, samples for laboratory control activities required under § 1120.68(b)(2) would need to follow an established sampling plan to ensure that samples being tested or evaluated are representative of the material being sampled (*i.e.,* the batch or part of the batch).

Third, proposed § 1120.68(b)(3) would require laboratory controls to include demonstration of analytical control, which means a laboratory must be able to show that its laboratory method and instrumentation reliably generate accurate and valid results. Demonstration of analytical control can be shown using a variety of quality control activities including but not limited to the use of certified reference materials, positive and negative controls, replicate testing, and/or internal standards. Quality control activities should be appropriate for the type and frequency of testing, suitable to monitor the analytical performance of the method and instrumentation used by the laboratory, and enable the laboratory to determine if the test yielded the expected result or response. One way to demonstrate compliance with this requirement would be to generate and maintain a quality control chart, which tracks and assesses results of quality control sample analysis with known amounts, to demonstrate analytical control of the equipment and test method. Demonstration of analytical control allows a tobacco product manufacturer to have confidence in the test sample measurements and investigate any anomalies early in the production process (*e.g.,* Refs. 142 and 143).

Under this proposed provision, for example, if a tobacco product manufacturer uses a laboratory to test or measure the moisture content of a cigarette as part of its acceptance activities to ensure that the product meets established specifications, a scientifically valid laboratory method would have to be used, such as the Weighing-Drying-Method with Oven and Balance, described in the Tobacco Moisture, Water and Oven Volatiles CORESTA Technical Report (Ref. 138). In addition, a sampling plan would have to be used to collect representative samples based on a valid scientific rationale, such as ISO 8243:2013 (*e.g.,* Ref. 144).

Proposed § 1120.68(c) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under proposed § 1120.68. Under this paragraph, records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculation necessary to reconstruct the results. As stated elsewhere in this preamble, for purposes of proposed part 1120, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. Whether the laboratory control activities are conducted by the tobacco product manufacturer or contracted out to another facility, the manufacturer would be responsible for ensuring laboratory records, including results, are maintained in compliance with proposed §§ 1120.68(c) and 1120.122. These records could be included directly in the relevant production record or cross-referenced in another record that is readily accessible for inspection.

This proposed provision would help assure that the public health is protected. Laboratory controls, such as those used for acceptance activities, are important analytical tools for evaluating and testing a tobacco product to determine if it conforms to specifications established in the MMR, which could help to minimize the harm to public health associated with nonconforming products. For example, a smokeless tobacco product that does not conform to established pH specifications could adversely affect public health because it may have a more rapid rate of nicotine delivery and absorption, which can lead to increased dependence (Refs. 6 and 19).

This proposed provision also would require tobacco product manufacturers to control the laboratory activities that are part of the production process, which would further help to protect against the manufacture of a nonconforming product. For example, a tobacco product manufacturer may determine that monitoring the water content by measuring oven volatiles in the production process is necessary to control the level of microorganisms. Laboratory controls would ensure that the laboratory method used to monitor and control the moisture content in the production process is maintained within production process specifications, minimizing the chance for development of potentially harmful microorganisms.

In addition, the Agency believes that the proposed laboratory controls requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. These proposed requirements would enable the Agency to monitor and confirm that tobacco products are not manufactured in a manner that causes them to become adulterated under section 902(1) through (3) of the FD&C Act, that

tobacco products conform to specifications established in their MMRs, that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for exemption from SE, PMTA, MRTPA), and that pre-existing products are manufactured consistent with their original characteristics.

5. Production Record

Proposed § 1120.70(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that a production record is prepared for each batch of finished or bulk tobacco products to demonstrate conformity with the requirements established in the MMR in accordance with § 1120.44. These proposed requirements are generally consistent with the practices of manufacturing establishments that follow ISO 9001. The production record could consist of a single record or compilation of records that represent the complete production history of the finished or bulk tobacco product by batch, including identification of all of its components or parts, ingredients, additives, and materials (*e.g.,* Ref. 145).

Proposed § 1120.70(a) also would require that designated personnel review and approve the production record for release of each batch of finished and bulk tobacco products into distribution. This requirement is intended to ensure that each batch is acceptable for release into distribution (*e.g.,* that the products conform to MMR specifications; there were no unaddressed nonconformities as a result of deviations from process specifications or process controls; and the manufacturer has completed all acceptance activities and the results demonstrate that the acceptance criteria were met). The review and approval could take place at the end of manufacturing or at the end of stages of the production process such as, for example, primary, making, and packing stages in cigarette production.

Proposed § 1120.70(b)(1) through (7) would require that the production record include, or refer to the location of, certain information. Proposed § 1120.70(b)(1) would require the production record to include the manufacturing code of the finished or bulk tobacco product, which is defined in proposed § 1120.3 to include the manufacture date and batch number (see also proposed § 1120.96). This information is needed to identify affected tobacco product, for example, during a tobacco product complaint and/or nonconforming product investigation. A tobacco product manufacturer could also choose to include manufacturing time in the production record to further narrow the scope of any nonconforming product investigation. In this context, ''manufacturing time'' generally refers to the time that the finished or bulk tobacco product was packaged (*e.g.,* designated by year/month/date/hour/minute).

Proposed § 1120.70(b)(2) would require the production record to include the quantity of finished or bulk tobacco product manufactured in the batch. This information would be helpful for conducting tobacco product complaint and nonconforming product investigations because it would help determine how many tobacco products may be affected and, therefore, the scope of the investigation.

Proposed § 1120.70(b)(3) would require the production record to identify the major equipment and processing lines used in manufacturing the batch of finished or bulk tobacco product. If a tobacco product manufacturer has more than one piece of major equipment and/or processing line, this provision would require the manufacturer to document the specific major equipment and/or processing line that was used in the manufacture of the batch. This information would help to determine whether a nonconforming product is attributable to an issue with a particular piece of equipment or processing line and help determine the scope of product that might be affected.

Proposed § 1120.70(b)(4) would require that the production record also include records of any activities performed under proposed part 1120 necessary to demonstrate that the batch of finished or bulk tobacco product was manufactured to conform with the MMR requirements established under proposed § 1120.44. The records to be maintained in a production record under paragraph (b)(4) include purchasing records, acceptance activity records, continued process verification records, laboratory testing records, reprocessing and rework records, and packaging and labeling records. To the extent that these records may overlap with other records required under proposed part 1120, the manufacturer need not maintain duplicate copies in the production record but may instead simply cross-reference the location of the relevant records. We note, relatedly, that the records would not have to be physically located in the same place but the location of all relevant records must be included in the production record, and the records must comply with the requirements in proposed § 1120.122 (*e.g.,* the records must be readily accessible to responsible officials of the tobacco product manufacturer and to FDA).

Proposed § 1120.70(b)(5) would require the production record to include all unique identifiers of all accepted incoming tobacco products, including components or parts, ingredients, additives, and materials, used in the manufacture of the batch of finished or bulk tobacco product. This information could help a tobacco product manufacturer or FDA to determine if there is a problem with a particular component or part, ingredient, additive, or material and to establish traceability to identify other affected tobacco products.

Proposed § 1120.70(b)(6) would require that, if any finished or bulk tobacco product was used in the manufacture of the batch, the manufacturing code for that finished or bulk tobacco product must be included in the production record. For example, if a finished tobacco product manufacturer uses bulk tobacco product from a supplier, under § 1120.70(b)(6), the production record for the batch of finished tobacco product must include the manufacturing code for the bulk tobacco product (as received from the supplier and provided on the label of the bulk product). Similarly, if returned and reworked finished product is used in the subsequent manufacture of another finished product, under § 1120.70(b)(6), the production record for the subsequent finished product must include the manufacturing code of the incorporated returned and reworked product. We note that the requirement in proposed § 1120.70(b)(6) is distinct from and in addition to the requirement in proposed § 1120.70(b)(1) that the production record for each batch of finished or bulk tobacco product include the manufacturing code assigned by the manufacturer for that finished or bulk tobacco product. This information is needed to establish traceability and help identify affected tobacco products during a tobacco product complaint and/or nonconforming product investigation.

Proposed § 1120.70(b)(7) would require actual or copies of the packaging, labeling, and labels (as defined in proposed § 1120.3) used with the finished and bulk tobacco product, including inserts and onserts that accompany the product.

Finally, proposed § 1120.70(b)(8) would require the name(s) and signature(s) of the designated individual(s) reviewing and approving the production record for release of the batch of finished or bulk tobacco

product into distribution. The designated individual can perform the function of a gatekeeper by conducting a final review and approval of the production record for the batch for release into distribution. Alternatively, review and approval of the relevant portions of the production record can be conducted in stages. If review and approval is performed in stages throughout the production process, the manufacturer could also perform a final review and approval of the production record to verify that approvals of all production process stages had been made and documented.

The proposed production record requirements would help assure that the public health is protected. The proposed requirements would ensure that tobacco product manufacturers review and approve the production record prior to the release of each batch of finished and bulk tobacco product. The manufacturer would ensure that all records required to be included in the production record (*e.g.,* records from acceptance activities) have been included, or their location referenced, and that the production record demonstrates that the batch of finished or bulk tobacco product conforms to the MMR. These requirements would help prevent the distribution of nonconforming product.

In addition, the proposed production record contents are essential to the conduct of adequate tobacco product complaint and nonconforming product investigations to identify the scope and cause of an issue and ensure traceability to determine affected tobacco products. For example, if there are complaints that report a particular problem, review of the relevant production records (*e.g.,* manufacturing code, identification of major equipment and processing lines) can help determine the scope of the problem (*e.g.,* whether it is limited to a specific piece of equipment or processing line or certain production batches, or whether it includes all products from the establishment), the cause, and the quantity of affected tobacco product manufactured. If a manufacturer has to initiate a corrective action such as a recall, the manufacturing code included in the production record could also be used to identify the corresponding distribution records to help determine where the affected products were distributed.

The proposed production record requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, information regarding the identity and amount of all components or parts, ingredients, additives, and materials used in the manufacture of a finished or bulk tobacco product could be used to confirm ingredient listings submitted to FDA under section 904(a)(1) of the FD&C Act. Documenting in the production record the packaging, labeling, and labels used with finished tobacco products also would help enable FDA to determine if the tobacco products display required warning statements and are in compliance with the MRTP provisions in section 911 of the FD&C Act (21 U.S.C. 387k) and relevant requirements of section 903(a)(2) of the FD&C Act.

6. Sampling

For any sampling performed under proposed part 1120, proposed § 1120.72 would require finished and bulk tobacco product manufacturers to establish and maintain an adequate sampling plan using representative samples. These proposed requirements are similar to those in other FDA-regulated industry manufacturing regulations. To comply with this requirement, each manufacturer would be required to create a written sampling plan using representative samples, implement and follow the sampling plan, and update the sampling plan as needed. The proposed sampling requirements in proposed § 1120.72 would apply to all sampling performed under proposed part 1120, including sampling used for acceptance activities, process control monitoring, and continued process verification. Acceptance sampling is performed to determine the disposition of products tested (*e.g.,* accept, reject) whereas statistical process control and the sampling associated with monitoring a process are used to distinguish between variation that is inherent in the process and variation induced by some external factor that would result in nonconforming product.

A sampling plan is a written, detailed document that describes: (1) the purpose of the sampling, (2) the scientific technique or method used to establish the number of samples, including an explanation of how the sample size is representative of the material being sampled, and (3) the method of sampling. A sampling plan is essential to ensure that sampling is reliable, consistent, replicable, and suitable for its intended purpose. Under the proposed rule, manufacturers could tailor their sampling plans to specific activities and purposes. For example, a sampling plan for an acceptance activity could be different than one for monitoring whether a production process remains in a state of control or for continued process verification to detect sources of variability.

The basic principles of an adequate sampling plan include the following: the samples are representative of the batch or quantity being sampled, the number of samples is based on a valid scientific rationale, and the number of samples is sufficient for the intended purpose. ''Valid scientific rationale'' refers to scientific techniques or methods used to establish the number of representative samples and should take into account tolerance for variability, confidence levels, and the degree of precision required (Refs. 105, 107, 108). FDA believes that requiring the number of samples to be based on a ''valid scientific rationale'' would provide manufacturers with the flexibility to determine the appropriate number of representative samples for any sampling plan. While FDA is proposing this flexibility, this provision would require that manufacturers have support for the scientific technique or methods used to establish the number of representative samples used and to show that the sampling size is representative of the material being sampled.

Proposed § 1120.72(a) through (c) specifies the required elements of a sampling plan. First, proposed § 1120.72(a) would require the sampling plan to describe the intended purpose of the sampling (*e.g.,* product acceptance, monitor a production process, or detect sources of variability). Second, proposed § 1120.72(b) would require the plan to describe the scientific technique or method used to establish the sample size, including an explanation of how the sample size is representative of the material being sampled. Examples of scientific techniques or methods for sampling can include the ''ISO 2859 series of standards for sampling procedures for inspection by attributes,'' as well as ANSI/American Society for Quality (ASQ) Z1.4 (Refs. 146 and 125). Information regarding the scientific techniques and methods used would be required to include an explanation of the sample size (*i.e.,* the quantity or amount of product to be sampled) and how the sample size is representative of the material being sampled. The sample size would need to be sufficient for the intended purpose of the sampling plan and analysis to be performed. Third, proposed § 1120.72(c) would require the plan to describe the method of sampling. This refers to when and how samples are collected. For example, CORESTA Recommended Method No 24—Cigarettes—Sampling, A.3 states that samples should be drawn from one or more cartons of cigarettes at random from each sampling point to form the necessary gross and there should be at

least 10 sampling points distributed between factories where the cigarettes are made (Ref. 105).

The proposed representative sample requirements would help assure that the public health is protected by ensuring that any sampling performed under proposed part 1120 is scientifically sound and appropriate for its intended purpose and does not erroneously support the release of a batch containing tobacco products that do not conform to established specifications. If a sampling plan is not adequate, the results of an acceptance activity may not accurately demonstrate whether the batch meets established specifications, the established production process may not be properly controlled, and a validated process may not be adequately monitored to detect sources of variability, all of which could result in the manufacture and distribution of nonconforming product.

The proposed sampling requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Appropriate sampling methods would help manufacturers ensure that the new tobacco products and MRTPs they manufacture meet the specifications described in their applications (*i.e.,* SE report, request for exemption from SE, PMTA, MRTPA) and that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics.

7. Nonconforming Tobacco Product

Proposed § 1120.74 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the control and disposition of nonconforming tobacco product. A nonconforming tobacco product is defined as any tobacco product that does not meet a product specification as set by the MMR (see proposed § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or is a contaminated tobacco product. These procedures are necessary to help prevent the distribution of nonconforming tobacco products, which could pose risks not normally associated with tobacco products, by ensuring that all potential nonconforming products are identified, segregated, and investigated, and that appropriate disposition and followup is taken for products determined to be nonconforming. These provisions are also intended to help manufacturers determine the extent of any nonconformity and, in cases in which nonconforming product has already been released for distribution, determine where it was distributed. These proposed requirements are generally consistent with the practices of manufacturing establishments that follow ISO 9001 and the industry recommendations.

These proposed requirements would be applicable throughout the manufacturing process. For example, if an ENDS manufacturer determines through its in-process product acceptance activities that the liquid nicotine contains contaminants such as metal or silicate particles (known to cause respiratory disease and distress), the liquid nicotine would be a nonconforming product and would have to be handled according to the procedures outlined in proposed § 1120.74 (Ref. 2). Similarly, if an ENDS manufacturer determines through its process controls that the liquid nicotine concentration does not meet the concentration specification established in its MMR, the liquid nicotine would be a nonconforming product and the manufacturer would have to identify, segregate, investigate, and determine its disposition (*e.g.,* rework as appropriate or discard) in accordance with proposed § 1120.74(c) (Ref. 5). As another example, if a smokeless tobacco product manufacturer determines through its tobacco product acceptance activities that its chewing tobacco is contaminated with aflatoxins (Ref. 17), the manufacturer would be required to follow its nonconforming product procedures in accordance with this provision.

Proposed § 1120.74(a) would require finished and bulk tobacco product manufacturers to identify and segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition. This requirement would be triggered upon discovery of a potential nonconforming product. For example, if a manufacturer establishes acceptance activities to visually inspect incoming tobacco for the presence of mold, and a product appears to be discolored or blighted, the manufacturer would determine that the tobacco may be nonconforming and therefore subject to this provision. If an ENDS manufacturer performs laboratory testing on the nicotine concentration of an e-liquid as part of acceptance activities and the testing results do not conform to the established specification and acceptance criteria, the manufacturer would determine that the e-liquid is a potential nonconforming product that must be identified and segregated. If a tobacco product was manufactured under conditions outside of an established production process specification where failure to meet the process specification is reasonably likely to cause the tobacco product to fail to meet a product specification, the product should be treated as a potential nonconforming product.

Identification of potential nonconforming product can be accomplished in many ways (*e.g.,* applying a label with the relevant information directly to the product container; or, if an electronic system is utilized, associating the nonconforming product information with the relevant barcode). Identification is a critical first step to preventing further processing, production, or distribution of potential nonconforming tobacco product.

Proposed § 1120.74(a) would also require finished and bulk tobacco product manufacturers to segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition. This provision would require potential nonconforming product to remain segregated pending an investigation until it is determined to be conforming. If a potential nonconforming product is determined to be nonconforming, it would need to remain segregated throughout investigation and disposition, including any rework. For purposes of proposed part 1120, ''segregation'' means setting the identified potential nonconforming product apart from other product (*i.e.,* placing it away from conforming in-process material). This segregation could be accomplished by placing it in a quarantined or specifically marked-off area. Manufacturers should use prudence and segregate potential nonconforming tobacco product in a manner that is appropriate, given the nature of the potential nonconformity. For example, if a product is potentially nonconforming because it may be contaminated with pests, pathogens, or other substances that are likely to spread, it should be segregated and stored in a manner that prevents contamination of other tobacco products.

Proposed § 1120.74(b) would require finished and bulk tobacco product manufacturers to investigate all potential nonconforming tobacco products. The purpose of the investigation is to determine whether the product is in fact nonconforming and, if it is found to be nonconforming, to determine the scope and cause of the nonconformity, and the risk of illness or injury it poses. Under proposed § 1120.74(b)(1), in order to determine if

the product is nonconforming, FDA is proposing to require that the investigation include an examination of relevant production processes and controls, laboratory testing, complaints, and any other relevant records and sources of information.

For example, in accordance with proposed §§ 1120.66(a)(3) and 1120.74(b), if there was a deviation from a production process, a tobacco product manufacturer would be required to conduct an investigation to determine if the production process deviation resulted in a nonconforming product. For example, if the fermentation of a tobacco blend deviates from established production processes and controls for fermentation, such as maintaining temperature and humidity through specified turn cycles necessary to meet a pH specification, the tobacco product manufacturer would be required to perform an investigation to determine if the deviation resulted in a nonconforming product.

Similarly, if a manufacturer uses a laboratory to perform product acceptance activities, and there is an out-of-specification (OOS) laboratory test result, the manufacturer would need to investigate the OOS test result under proposed § 1120.74(b) to determine whether the product is nonconforming or the OOS result is due to another cause such as laboratory error. Under proposed § 1120.74(b)(1), the investigation would be required to include an examination of relevant production processes and controls and any other relevant records and sources of information such as the laboratory method and review of initial testing and calibration of the laboratory equipment. Such an investigation could determine that the OOS test results came from an aberration of the measurement process (*e.g.,* laboratory error, defective testing equipment, or deviation from an established laboratory test method) and that the potential nonconforming product is not nonconforming. Alternatively, an investigation could conclude that the OOS test result was valid and that the product was nonconforming as a result of the manufacturing process.

If a tobacco product is determined to be nonconforming, under proposed § 1120.74(b)(2), the investigation also would be required to determine the scope and cause of the nonconformance and the risk of illness or injury posed by the nonconformance. Examination of relevant production processes and controls and any other relevant records and sources of information could help a manufacturer determine if any other batches are affected or if nonconforming product has been distributed. For example, if the investigation of a nonconforming product determines that the cause is due to fragments from a cutting blade, the manufacturer may need to investigate other batches on which the cutting blade was used since it was last inspected and take appropriate follow up action. For any product determined to be nonconforming, documentation of the investigation activities under proposed § 1120.74(d) should include the product name (brand and sub-brand), additional product identification, and quantity of nonconforming tobacco product. The additional product identification should include all unique identifiers associated with the tobacco product and, if applicable, the manufacturing code of the finished or bulk tobacco product.

The proposed rule would also require that, for products determined to be nonconforming, the investigation include an examination of the risk of illness or injury posed by the nonconformance, because this risk would be relevant to the manufacturer's disposition decision under proposed § 1120.74(c). Furthermore, this information can feed into the manufacturer's risk management process under proposed § 1120.42.

Under proposed § 1120.74(b), an investigation would be required to be performed for all potential nonconforming products. However, if a previous investigation has been completed and it is determined to be applicable to the current investigation, the results and followup of the previous investigation could be cross-referenced and applied to the current investigation. In other words, if the cause of a nonconforming product is determined to be the same as that of a previous nonconforming product, the manufacturer could cross-reference the results of the previous investigation and would not need to repeat aspects of the investigation that would be redundant.

Proposed § 1120.74(c) would require finished and bulk tobacco product manufacturers to determine the disposition of all nonconforming tobacco products and to conduct any necessary follow up action. Under proposed § 1120.74(c), nonconforming product could not be released for distribution without rework or an adequate justification. Thus, nonconforming product could be reworked as appropriate under proposed § 1120.78, distributed with an adequate justification (as explained below), or discarded. If a manufacturer determines that nonconforming product can be reworked, the disposition decision should address how the rework will correct the nonconformity without adversely affecting the product. For example, if an ENDS manufacturer decides to rework a nonconforming circuit board by resoldering a joint, the manufacturer should document how such rework does not adversely affect the circuit board by melting or delaminating board components.

A manufacturer may determine that a nonconforming tobacco product can be released for distribution without rework; however, proposed § 1120.74(c) would require the manufacturer to provide an adequate written justification before releasing such product. An adequate written justification would be required to address why releasing the product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded. For example, if a manufacturer determines that a product is nonconforming because of a minor discrepancy in the color of its packaging (*e.g.,* Pantone 2415 C vs. an established specification of Pantone 2415 CP) and that the product can be released for distribution without rework, the manufacturer could provide an adequate written justification (*i.e.,* explain that the minor color discrepancy will not increase the risk of illness or injury or render the product adulterated or misbranded) and release the nonconforming product. However, nonconforming product that would increase the risk of illness or injury, or that would result in the tobacco product being adulterated or misbranded would not be acceptable for release without rework. For example, if a nonconformity results in a modification of a product that would require a new marketing application under section 905 or 910 of the FD&C Act and make the product misbranded under section 903(a)(6) of the FD&C Act or adulterated under section 902(6)(A) of the FD&C Act, the nonconforming product could not be released for distribution without rework. Similarly, a tobacco product that becomes contaminated by glass fragments from an unprotected light fixture would present an increased risk of injury to the user that would warrant discarding the product as it may not be possible for it to be reworked.

Proposed § 1120.74(c) would also require finished and bulk tobacco product manufacturers to conduct any necessary followup actions. Follow up actions could include initiating a CAPA under proposed § 1120.16 and taking appropriate corrective action on other affected batches. If nonconforming product has already been distributed, the manufacturer could initiate a recall.

Necessary followup should be informed by the results of the investigation under proposed § 1120.74(b); for example, the risk of illness or injury posed by the nonconformance may affect the type of CAPA to be taken.

Proposed § 1120.74(d) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. This provision would require that such records include the date and time of the activity, the individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in this preamble, for purposes of this proposed part 1120, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. For any product determined to be nonconforming, the records should document the product name (brand and sub-brand), any additional product identification information (*e.g.,* manufacturing code(s), batch number, or unique ID as applicable), and the quantity of nonconforming tobacco product. This information is important for verifying that all potential nonconforming product is properly handled, that nonconforming product investigations are appropriately thorough and complete, and that disposition decisions are made to prevent the release of nonconforming product for distribution and are properly justified.

In addition to helping to prevent the distribution of nonconforming product, the proposed nonconforming product requirements would help assure that the public health is protected by requiring tobacco product manufacturers to perform a systematic assessment of nonconforming product and take appropriate followup. Nonconforming product can result from a design problem, failure to meet tobacco product specifications, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate training, inadequate manufacturing methods and procedures, or improper handling of the tobacco product. The proposed provisions would require manufacturers to investigate the cause of nonconforming product and take appropriate followup, such as CAPAs, to eliminate or minimize future nonconformities. For example, if a cigarette manufacturer determined that a cigarette did not meet its filter pressure drop specification (a nonconformity that can expose consumers to increased risk of exposure to constituents compared to what would normally be expected from cigarette use (Ref. 147), these provisions would require that the manufacturer undertake a systematic assessment to determine the cause of the nonconformity and the need for CAPAs to be taken, which would help prevent the manufacture and sale of similar nonconforming product. If the results of acceptance activities demonstrate that the product does not meet the specification, the manufacturer would be required to take the steps to address nonconformities in accordance with proposed § 1120.74. Specifically, the manufacturer would need to identify and segregate the nonconforming product to prevent mixups and distribution of nonconforming product, investigate the nonconformity, and determine the disposition of the product.

As another example, where a tobacco product manufacturer determines that its product does not conform to established pH specifications, it would be required to comply with this proposed provision. The amount and speed of nicotine delivered by a tobacco product is related to the proportion of nicotine in a tobacco product and/or its emissions that is in the unprotonated or ''free-base'' form (also known as the un-ionized free-base form); therefore, a product that delivers more unprotonated nicotine at a faster rate is more addictive and toxic than other tobacco products. Because the pH scale is logarithmic, the proportion of unprotonated nicotine increases or decreases sharply with relatively small changes in pH. For example, at a pH of 7, about 7 percent of the nicotine is free; at a pH of 9 or more, 80 percent of the nicotine is in the free form. Tobacco and smoke pH appear to be controlled primarily by the use of ammonia compounds and other substances used in tobacco processing and final cigarette production, which serve to optimize the free nicotine levels (Ref. 6). Accordingly, a tobacco product's specifications (including the amount of ingredients, additives, and materials such as ammonia compounds) can affect the product's pH. A manufacturer's investigation and disposition of such nonconforming product would help to ensure that such products are not placed into distribution and that such nonconformities do not occur in the future, thereby helping ensure that consumers are not exposed to greater risks than those normally associated with the use of the product.

The proposed nonconforming product requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by providing thorough steps and actions to be taken on nonconforming tobacco products. These measures would help ensure that tobacco products that are nonconforming are either not placed into distribution or are reworked so that they conform to established specifications, including those provided by the manufacturer to FDA in any relevant tobacco product applications (*i.e.,* SE Report, request for exemption from SE, PMTA, MRTPA). In addition, they would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to finished tobacco products that may render them new tobacco products adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act.

8. Returned Tobacco Product

Proposed § 1120.76(a) would require each finished and bulk tobacco product manufacturer to establish and maintain procedures for the control and disposition of returned tobacco product. Returned tobacco products are commercially distributed finished or bulk tobacco products returned to the tobacco product manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or a member of the public. These proposed requirements are generally similar to practices of manufacturing establishments that follow ISO 9001.

Proposed § 1120.76(a)(1) would require finished and bulk tobacco product manufacturers to identify returned tobacco product with the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, and reason for return. Returned tobacco products should be identified using appropriate means such as a tag or label to prevent mixups and inadvertent use or distribution.

Proposed § 1120.76(a)(2) would require finished and bulk tobacco product manufacturers to segregate the identified returned tobacco product in a manner that prevents mixups and use of returned tobacco product prior to evaluation and disposition. Returned tobacco products could be segregated by being placed in a quarantined area or in an identified location that prevents mixups.

Proposed § 1120.76(a)(3) would require finished and bulk tobacco product manufacturers to evaluate identified returned tobacco product and determine its disposition (*i.e.,* discard,

rework, release for distribution). Evaluation is necessary to determine whether the returned product should be discarded, whether it is appropriate for rework under proposed § 1120.78, or whether the product can be released for distribution. If during an evaluation, a manufacturer determines that returned tobacco product is potentially nonconforming, the manufacturer would be required to follow its nonconforming product procedures in accordance with proposed § 1120.74. Under proposed § 1120.76(a)(3), tobacco product manufacturers would have flexibility to determine how to evaluate returned tobacco product. A tobacco product manufacturer could use inspection, testing, or other verification methods to evaluate the returned tobacco product and make an appropriate disposition determination. Returned tobacco product would be required to be discarded unless the manufacturer determines that it can be reworked, or released for distribution based on an adequate written justification. An adequate written justification would show that the returned product is not nonconforming or explain why releasing nonconforming returned product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded (see also proposed § 1120.74(c)).

In some circumstances, a manufacturer could determine that returned nonconforming product can be reworked to meet established specifications. For example, if a tobacco product is returned because the package contained an incorrect quantity, the manufacturer could repackage the product with the correct quantity. The release of nonconforming returned product for distribution should not occur except in limited circumstances where the manufacturer can provide an adequate written justification that addresses why releasing the product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded (see proposed § 1120.74(c)). For example, a manufacturer could release a returned product for distribution without rework if the product was mistakenly sent to a distributor or retailer and returned in unopened and intact packaging with no visible signs of damage or contamination.

FDA notes that when returned products are determined to be potentially nonconforming under proposed § 1120.74, or are associated with complaints under proposed § 1120.14 or with a CAPA under proposed § 1120.16, the requirements in those sections, including all investigation requirements, would apply and take precedence. If returned products are needed (*e.g.,* for product testing) in order to conduct an adequate investigation under those sections, a manufacturer should complete the investigation before discarding the returned product under proposed § 1120.76. For example, if a manufacturer determines that a returned product might contain a contaminant, it should keep the product and complete an investigation on the nature and scope of the contamination before the returned product is discarded.

If a tobacco product manufacturer's disposition decision is to rework the returned tobacco product, the rework would need to be performed in accordance with proposed § 1120.78.

Proposed § 1120.76(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in the preamble, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. In addition, records of evaluation and disposition would be required to include the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, reason for the return, disposition decision and any justification, and the name of the individual making the decision.

The industry GMP recommendations do not include returned product provisions. The Agency believes the proposed returned tobacco product requirements would help assure that the public health is protected by requiring that manufacturers of finished and bulk tobacco products evaluate returned tobacco products and adequately justify their disposition decisions. For example, FDA has learned that some tobacco products have been contaminated with insecticides, gasoline or diesel fuel, or other toxic substances during shipment (*e.g.,* Refs. 148 and 149). In addition, FDA is aware that tobacco products such as ENDS may be altered or customized by a vape shop, resulting in nonconformity, including contamination. If these products are returned to the manufacturer, this provision would help ensure that they are handled appropriately and that any subsequent distribution of the products is adequately justified.

The proposed returned tobacco product requirements would assure that the public health is protected and that products are in compliance with chapter IX of the FD&C Act by helping to prevent contamination and adulteration of tobacco products. Contaminated and adulterated tobacco products can adversely affect public health over and above the risk normally associated with the use of the product.

9. Reprocessing and Rework

Proposed § 1120.78 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for reprocessing and reworking tobacco product. These proposed requirements are similar to practices that are already being implemented by the tobacco industry, as FDA has observed during inspections, and to the practices of manufacturing establishments that follow ISO 9001. FDA has found that tobacco product manufacturers use reprocessing procedures in their manufacturing process (Refs. 150–154).

Proposed § 1120.3 defines ''reprocessing'' as using tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product. An example of reprocessing would be using tobacco recovered during the production process, such as cigarette tobacco recovered from the ripper short process (*e.g.,* Ref. 155) or tobacco recovered from smokeless tobacco cans that are rejected for being the incorrect weight, in the subsequent manufacture of cigarettes or smokeless tobacco cans that use the same tobacco blend. Proposed § 1120.3 defines ''rework'' as action taken on a nonconforming or returned tobacco product to ensure the product meets the specifications and other requirements in the MMR of a subsequently manufactured product before it is released for further manufacturing or distribution. An example of rework would be the repackaging or relabeling of a finished tobacco product due to nonconforming packaging or labeling.

Specifically, proposed § 1120.78(a)(1) would require the reprocessing and rework procedures to include evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual. Under proposed § 1120.78(a)(1), tobacco

product would be appropriate for reprocessing if it is uncontaminated and has the same specifications as those in the MMR of the subsequently manufactured tobacco product. For example, tobacco recovered through a ripper short process would be appropriate for reprocessing if it is uncontaminated and has the same tobacco blend/type, size, and length, as specified in the MMR of the subsequently manufactured tobacco product. Tobacco recovered from one brand of a finished or bulk tobacco product could be reprocessed for use in the subsequent manufacture of another brand/sub-brand of a finished or bulk tobacco product if it has the same tobacco blend/types, cut size, and length and otherwise meets the MMR specifications for the other brand/sub-brand. However, mentholated tobacco, for example, would not be appropriate for reprocessing in the subsequent manufacture of a nonmentholated finished or bulk tobacco product.

A tobacco product would be appropriate for rework if further manufacturing can correct the nonconformity and the product could meet the specifications and other requirements in the MMR of a subsequently manufactured tobacco product. For example, if a tobacco product is nonconforming because of a contaminant, it would be appropriate for rework if further manufacturing could eliminate the contaminant and the tobacco product could meet the specifications and other requirements in the MMR for the subsequently manufactured product.

The evaluation required under proposed § 1120.78(a)(1) could be done by conducting testing or other inspection or verification activities, or by providing an adequate written justification for why the tobacco product is appropriate for reprocessing or rework. FDA has observed on inspections that reprocessing often occurs in the following in-line situations: incomplete cigarettes produced by a maker machine (*e.g.,* loose ends, ripper shorts, paper damage, or empty tip (no filter attached)); and smokeless tobacco cans that are rejected for missing or having an incorrect label or being the incorrect weight. In these types of situations, manufacturers typically determine that the tobacco is appropriate for reprocessing without further investigation or testing because it is uncontaminated and can be directly recovered from manufacturing for use in the subsequent manufacture of finished or bulk tobacco products. For example, if the manufacturer decides to reprocess tobacco from unformed cigarettes that are rejected by the maker equipment, under proposed § 1120.78(a)(1), the manufacturer would be required to evaluate the tobacco to ensure that it is appropriate for reprocessing. The evaluation could determine that the recovered tobacco is appropriate for reprocessing because these unformed cigarettes were collected directly from the maker and, therefore, further testing is not necessary to show that the tobacco is not contaminated and conforms to the specifications established in the MMR for the subsequently manufactured product. The manufacturer should provide an adequate written justification for its determination that is appropriate to reprocess the recovered tobacco, either in its reprocessing procedure or on an ad hoc basis. If the manufacturer chooses to reprocess tobacco products out-of-line (*i.e.,* tobacco not recovered directly from the production line), it should determine whether the evaluation should include testing the product to ascertain eligibility for reprocessing (*e.g.,* testing to ensure that the product is not contaminated).

A manufacturer would also have to perform an evaluation under proposed § 1120.78(a)(1) to determine whether tobacco product is appropriate for rework. For example, if finished packages of cigars are rejected for being the incorrect weight, a manufacturer would have to evaluate the nonconforming product to determine if it is appropriate for rework. The evaluation could determine that the nonconformity is due to the package having four cigars instead of the required five cigars, and that the product can undergo repackaging to address the nonconformity and meet the specifications and other requirements in the MMR for the subsequently manufactured product. In some cases, an evaluation may show that a product is not appropriate for rework. For example, an evaluation of returned tobacco product may determine that it is not appropriate for rework because further manufacturing cannot remove a contaminant, such as an insecticide (*e.g.,* Ref. 148).

Proposed § 1120.78(a)(2) would require the reprocessing and rework procedures to detail the production processes, including process controls, in accordance with proposed § 1120.66(a), and acceptance activities, in accordance with § 1120.64(c), used to ensure the reprocessed or reworked tobacco conforms to the requirements established in the MMR for the subsequently manufactured product. Usually, the production processes and controls used for reprocessing and rework would be the same as those used for the subsequently manufactured product under proposed § 1120.66(a) and reflected in its MMR under proposed § 1120.44(a)(2). However, there may be instances in which a manufacturer uses different production processes or process controls when reprocessing or reworking tobacco product. If reprocessing or rework involves different production processes and controls, proposed § 1120.78(a)(2) would require that reprocessing and rework procedures include these different production processes and controls. For example, if a manufacturer recovers tobacco product from a packing and labeling machine, determines that the product is nonconforming because it has incorrect labels, and decides to rework it using a manual relabeling process, the manufacturer would be required to include in its reworking procedures the production processes and controls for the manual relabeling process used to ensure that the subsequent reworked finished tobacco product conforms to the MMR specifications.

Proposed § 1120.78(b) would establish the requirement to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in this preamble, FDA interprets ''reconstruct'' to mean the ability to recreate the results by analyzing all data, including source and metadata data, and records, including calculations.

Additionally, proposed § 1120.78(b) would require that the production record of any finished or bulk tobacco product that includes reprocessed or reworked product include the amount, any unique identifier(s) assigned under proposed § 1120.64(b), any batch number, and any manufacturing code associated with the reprocessed or reworked product. These requirements are necessary to enable the tobacco product manufacturer to trace tobacco products consisting of (in whole or in part) reprocessed or reworked material and take appropriate corrective action, such as a recall or changes to procedures, if these products are determined to be nonconforming following reprocessing or rework. Reprocessing or rework records would be required to be maintained in the tobacco product's production record to show that the product conforms to the MMR.

The proposed reprocessing and rework requirements would assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act by helping to ensure that reprocessed or reworked tobacco products are not contaminated or adulterated or misbranded and meet the requirements in the MMR for the subsequently manufactured product. They would also help maintain traceability in case there is nonconformity as a result of ineffective reprocessing or reworking processes or procedures and corrective action is needed.

F. Packaging and Labeling Controls

1. Packaging and Labeling, and Repackaging and Relabeling, Controls

Proposed § 1120.92 would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control packaging and labeling activities to prevent mixups and to ensure that all packaging and labeling are approved for use by the manufacturer and comply with all requirements of the MMR (see proposed § 1120.44) as well as all other applicable requirements of the FD&C Act, CSTHEA, FCLAA and their implementing regulations. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001 and to the proposed packaging and labeling controls in the industry recommendations.

Other applicable requirements of the FD&C Act, CSTHEA, FCLAA, and their implementing regulations include, among others: requirements related to false or misleading labeling of tobacco products under section 903(a)(1); requirements for including certain information on the label of tobacco products in package form under section 903(a)(2) of the FD&C Act; and package warning statement requirements for cigarettes under section 4 of FCLAA, for smokeless tobacco under section 3(a) of CSTHEA, for cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars under § 1143.3(a) (21 CFR 1143.3(a)), and for cigars under § 1143.5(a). This includes warning rotation plan requirements for packages pursuant to section 4(c)(1) of FCLAA, section 3(b)(3)(C) of CSTHEA and § 1143.5(c). For example, under § 1143.5, packaging for cigars is required to contain certain warning statements in accordance with an FDA-approved warning plan. Accordingly, under this proposed provision, finished cigar manufacturers would have to establish and maintain procedures to control packaging and labeling activities to ensure that the correct required warning statement is applied to the cigar package, that the formatting requirements are met, and that the warnings on the package label follow the approved warning plan (§ 1143.5). See also proposed § 1120.98 for related requirements about warning plans.

As set forth in proposed § 1120.44(a)(3), the MMR would be required to include all packaging, labeling, and labels approved by the manufacturer for use with the finished or bulk tobacco product. The packaging and labeling control procedure requirement proposed in this section would ensure that only the approved packaging, labeling, and labels are used on finished and bulk tobacco products.

A tobacco product manufacturer could control packaging and labeling operations to prevent mixups using a variety of techniques. For example, a manufacturer could release approved and accepted packaging and labeling for each production batch (*i.e.,* a manufacturer could release the packaging and labeling in the same manner as it would release received components from a supplier that pass acceptance activities). Product acceptance could utilize verification activities, such as visual inspection and optical scanners, to inspect finished and bulk tobacco products to ensure the use of correct packaging and labeling, including correct package warning statements on finished products. Outdated or obsolete packaging and labeling should be destroyed.

Proposed § 1120.92(a)(1) would require that the packaging and labeling control procedures address label integrity. Specifically, this provision would require that labels be indelibly printed on or permanently affixed to finished and bulk tobacco product packages so they remain legible, prominent, and conspicuous during the customary conditions of processing, packing, storage, handling, distribution, and use. For a finished tobacco product, permanently affixed means the label must remain on the product package through the expected duration of use of the tobacco product by the consumer. For a bulk tobacco product, permanently affixed means the label must remain on the product package until the receipt by the subsequent manufacturer (*e.g.,* finished tobacco product manufacturer, packager or labeler). These label integrity requirements are intended to ensure that labels remain affixed to the tobacco product, and that the information contained on the label remains visible and readable and is not adversely affected by conditions such as ink bleeding, adhesion loss, or fading.

Proposed § 1120.92(a)(2) establishes design and construction requirements for packaging and labeling and for storage and shipping cases and containers. Specifically, proposed § 1120.92(a)(2)(i) would require that a manufacturer has procedures that ensure that a product's packaging and labeling do not contaminate or otherwise render the tobacco product adulterated or misbranded. To comply with this requirement, as part of its packaging and labeling procedures, a tobacco product manufacturer could evaluate the packaging materials to assess toxicological issues and verify that the material would not contaminate the tobacco product (Ref. 156). For example, packaging or label solvents such as benzene, toluene, methyl ethyl ketone, methyl cellosolve, and cellosolve are among the chemicals that can transfer from packaging materials to tobacco products and cause contamination (*e.g.,* Refs. 157–159). This proposed provision is intended to ensure that, among other things, a product's packaging and labeling do not render the product adulterated due to the use of these types of chemicals.

Proposed § 1120.92(a)(2)(ii) would require that the manufacturer has procedures that ensure storage and shipping cases or containers of finished or bulk tobacco products are designed and constructed to protect against contamination and adulteration of finished and bulk tobacco products during the customary conditions of storage, handling, and distribution. For example, if tobacco products are customarily stored, handled, or shipped in conditions where the tobacco product can be exposed to oils, hazardous materials, or insanitary conditions, the storage and shipping cases or containers would have to be able to protect the products from becoming contaminated or adulterated. Also, if customary environmental conditions of storage, handling, and distribution (such as temperature, moisture, and humidity) can contaminate or adulterate the tobacco products (*e.g.,* mold contamination), the storage and shipping cases or containers would have to protect the products from these conditions adequately.

Proposed § 1120.92(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. According to this provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was

met, and any data or calculations necessary to reconstruct the results.

These proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act. Proper packaging and labeling of finished and bulk tobacco products are necessary to avoid mixups and to ensure that the packaging and labeling do not contaminate or otherwise render the tobacco product adulterated or misbranded. If a manufacturer applies the wrong label to a tobacco product, the label may be false or misleading, rendering the product misbranded under section 903(a)(1) of the FD&C Act. Such a product could impact public health. For example, in the case of a mixup, if a manufacturer applies the wrong nicotine concentration label to an e-liquid such that the product contains significantly higher levels of nicotine than what is stated on the label, this can increase the risk of addictiveness.

Proper packaging and labeling of tobacco products play an important role in FDA's comprehensive public health approach to tobacco control. The Tobacco Control Act contains a number of provisions related to the packaging and labeling of tobacco products. For example, certain tobacco product labeling must be submitted to FDA when tobacco manufacturers register under section 905(i)(1) of the FD&C Act. Specimens of tobacco product labeling must also be submitted with PMTAs under section 910(b)(1)(F) of the FD&C Act. Similarly, sample product labels and labeling must be included in MRTP applications under section 911(d)(4) of the FD&C Act. Additionally, section 903(a)(1) of the FD&C Act includes provisions related to false or misleading labeling of tobacco products, such as, for example, labeling that fails to bear required health warning statements (see section 201(n) of the FD&C Act). In addition, FDA's Deeming Rule requires warning statements on the packages of all covered tobacco products, cigarette tobacco, and RYO tobacco, with limited exceptions (see part 1143). The packaging and labeling of tobacco products contain required warning statements that promote greater understanding of the risks associated with the use of tobacco products (Ref. 160). For a discussion regarding why health warnings are appropriate for the protection of the public health and the effectiveness of warning statements, please see the analysis in the proposed Deeming Rule (79 FR 23142 at 23163–65). Requiring that tobacco product manufacturers establish and maintain procedures to control packaging and labeling activities would help to ensure that the manufacturers successfully carry out the labeling requirements in the Tobacco Control Act.

Proposed § 1120.94(a) would require finished tobacco product manufacturers to establish and maintain procedures to control repackaging and relabeling activities. These procedures would be required to address all requirements described in proposed § 1120.92. The terms ''repackaging'' and ''relabeling'' describe activities in which the package or label of a finished tobacco product is subsequently changed or replaced. Repackaging and relabeling may be performed by the same person who originally packaged and labeled the product or by someone other than the original packager/labeler. For example, if a manufacturer receives returned tobacco products and determines that the products could be distributed with new packages or labels, the manufacturer would have to comply with this provision, among others. In addition, this proposed provision would apply to an importer that changes or replaces the packages or labels of imported finished tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, and to the proposed repackaging and relabeling provision in the industry recommendations.

Proposed § 1120.94(b) would require finished tobacco product manufacturers to maintain records of all activities required under this section. According to this provision, records must include the date and time, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Like the proposed packaging and labeling control requirements (discussed in the preceding section), these proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If a manufacturer applies the wrong label to the tobacco product, the product may be misbranded under section 903. In addition, if a finished tobacco product manufacturer recalls a product because the product was distributed with the wrong label, and determines that rework of that product is possible through repackaging or relabeling, the proposed requirements would help ensure that the reworked tobacco product conforms to the established specifications and other applicable requirements.

Proper packaging and labeling of tobacco products play an important role in FDA's comprehensive public health approach to tobacco control. The Tobacco Control Act contains a number of provisions related to the packaging and labeling of tobacco products (*e.g.,* sections 905(i)(1), 910(b)(1)(F), and 911(d)(4) of the FD&C Act), including provisions related to false or misleading labeling (section 903(a)(1) of the FD&C Act), such as labeling that fails to bear required health warning statements (see section 201(n) of the FD&C Act). For a discussion regarding why health warnings are appropriate for the protection of the public health and the effectiveness of warning statements, please see the analysis in the proposed Deeming Rule (79 FR 23142 at 23162). Requiring that tobacco product manufacturers establish and maintain procedures for repackaging and relabeling activities would help to ensure that the manufacturers successfully carry out the labeling requirements in the Tobacco Control Act.

2. Manufacturing Code

Proposed § 1120.96(a) would require that each finished and bulk tobacco product manufacturer apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001 and practices that FDA has observed during establishment inspections, as well as to the proposed requirements of the industry recommendations.

For a finished tobacco product, the manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label through the expected duration of a consumer's use of the tobacco product. For a bulk tobacco product, the manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label until receipt by the subsequent tobacco product manufacturer.

For example, under this proposed provision, a finished cigarette manufacturer, who sells individual packs of cigarettes as well as cartons of cigarettes, would be required to apply a manufacturing code to each carton and to each pack of cigarettes. Similarly, a smokeless manufacturer who sells individual cans of smokeless tobacco as well as multiple cans packaged together in a plastic sleeve would need to apply a manufacturing code to the sleeve and to each individual can. Some cigarette manufacturers already apply similar

codes on cartons of cigarettes, and some smokeless tobacco product manufacturers apply similar codes on the plastic sleeve that holds individual and multiple cans of smokeless tobacco. Since the carton and the sleeve are typically discarded by the consumer during use, this section also would require that the manufacturing code be applied on the individual cigarette pack and smokeless can. FDA has observed on inspections that many manufacturers apply a code to the packaging, labeling, or shipping containers of finished tobacco products, which may be discarded prior to a consumer's use or immediately upon opening by the consumer, but FDA believes this practice is not sufficient. Under the proposed provisions, if a user stores the tobacco product and then later experiences an injury or illness due to a hazard or contaminant, or has another health-related problem, the user would be able to notify the manufacturer of the affected product using the product's manufacturing code, even if the packaging sleeve has been discarded.

Proposed § 1120.96(b) would require that the manufacturing code for each finished and bulk tobacco product be permanently affixed, legible, conspicuous, and prominent. The code should be easily visible, and it should not be obscured or be able to be mutilated or removed in whole or in part. For example, a manufacturing code that is partially smudged and cannot be read in its entirety would not meet the proposed requirement. This proposed requirement would allow for ready identification of the manufacturing code during distribution and sale. It also would help FDA to identify and trace nonconforming or violative tobacco products and perform relevant inspections to determine the scope of the problem and recommend or require appropriate corrective action such as a recall or stock recovery.

Proposed § 1120.96(c) would require that the manufacturing code contain the following information listed in the following order: (1) the manufacturing date in two-digit numerical values in the month-day-year format (MMDDYY), and (2) the finished or bulk tobacco product batch number. FDA proposes to require the manufacturing code to include the batch number because the batch number is the common identifier for the product in the production and distribution records. Because the batch number would be documented in the production record (see proposed § 1120.70) and the production record would include all the relevant manufacturing information for the batch (*e.g.,* unique identifiers of incoming components, acceptance activities results, identification of major equipment and processing lines used in the manufacturing of the batch), the manufacturing code on the product package or label would establish a link to the manufacturing history of the product and, as discussed in proposed § 1120.104, to certain records of distribution.

The proposed manufacturing code requirement would help assure that the public health is protected by providing for tobacco product traceability. The manufacturing code would enable tobacco product manufacturers to determine the manufacturing and distribution history of finished and bulk tobacco products. If a product user becomes ill or injured due to a hazard or contaminant, or otherwise has a tobacco-related health problem, the user would be able to notify the manufacturer of the affected product using the product's manufacturing code. The manufacturer could use this information to review the production record as part of a complaint, nonconforming product, or CAPA investigation to determine the scope and cause of the issue. In addition, the manufacturing code would help the manufacturer determine the distribution history of the affected tobacco product if it needs to take a corrective action, such as a recall or stock recovery.

In addition, the proposed requirement would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If adulterated or misbranded products have been manufactured and distributed, the Agency can identify affected batches and take appropriate actions. For example, the manufacturing code would help FDA effectuate an order under section 908(a) of the FD&C Act to provide notification about tobacco products that present an unreasonable risk of substantial harm to the public health in order to eliminate such risk. This information would also help to effectuate an order under section 908(c) to recall tobacco products, where FDA finds that there is a reasonable probability that the tobacco product contains a manufacturing or other problem not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death. In addition, if FDA tests tobacco products at retail locations and determines that the products are adulterated or misbranded, it would be able to use the manufacturing code to conduct relevant inspections or investigations (*e.g.,* review production and distribution records) to determine the scope and cause of the issue and take appropriate action.

3. Warning Plans

Proposed § 1120.98(a) would require each finished tobacco product manufacturer that is required to comply with a warning plan for tobacco product packaging (under the FD&C Act, FCLAA, CSTHEA, or their implementing regulations) to establish and maintain procedures to implement the requirements of such warning plan. For example, under § 1143.5(c), certain cigar packages must bear warning statements that are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar, and randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, FDA. Proposed § 1120.98(a) would require cigar manufacturers that are required to comply with an FDA-approved plan under § 1143.5(c) to establish and maintain procedures to ensure that such a plan is implemented and followed. Similarly, finished cigarette and smokeless tobacco product manufacturers would have to establish and maintain procedures to ensure that warning plans for cigarette and smokeless tobacco product packaging required under FCLAA and CSTHEA are implemented and followed.

Under section 903(a)(1) of the FD&C Act, a tobacco product is deemed to be misbranded if its labeling is false or misleading in any particular. This could include, for example, a case in which a manufacturer includes the same single warning on all product packages, when there is a requirement to rotate a number of different warnings (see section 201(n) of the FD&C Act). This provision would help the Agency to ensure that tobacco product packaging displays all applicable required health warning statements. FDA has observed that some manufacturers do engage in activities that address warning plans but we have also found, during inspections, that some manufacturers do not have proper procedures in place at the manufacturing facility to ensure the warning statements are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of product, and randomly distributed in all areas of the United States in which the product is marketed (*e.g.,* Refs. 55 and 161) (see 15 U.S.C. 4402).

Manufacturers could adopt a number of practices to comply with applicable warning plans. For example,

manufacturers could order labels on which the warnings are printed in sequence on the label rolls such that, for a given production run, each of the warnings is applied equally. Alternatively, manufacturers could use multiple label rolls that contain one of the required warning labels and have a supervisor tasked with calculating and documenting when to switch the roll to ensure that the required warning labels are equally applied in a batch. Further, manufacturers could establish procedures that define the specific number of each of the required warning statements needed for printing or affixing to the label of each brand of product during the manufacturing process and outline procedures for shipment of the products to ensure random distribution. Such practices could be included in the procedures required in this proposed provision.

Under proposed § 1120.98(a), the warning plan procedures would be required to include the inspection of the packaging before distribution to ensure that finished tobacco product labels bear the required warning statements in accordance with the warning plan. For example, FDA is aware that some manufacturers use visual inspection or electronic optical scanners to perform inspection of packaging and labeling to confirm that the correct warning statements have been applied.

Proposed § 1120.98(b) would require finished tobacco product manufacturers that are required to comply with a warning plan for tobacco product packaging (under the FD&C Act, FCLAA, CSTHEA, or their implementing regulations) to maintain records that demonstrate that they are in compliance with the warning plan. For example, if the manufacturer must comply with a cigar warning plan under § 1143.5, this provision would require the manufacturer to maintain records that demonstrate that the required warning statements are randomly displayed in each 12-month period, in as equal number of times as possible on each brand of cigar packaging. Such records also would need to demonstrate that the required warning statements on packaging are randomly distributed in all areas of the United States in which the cigar is marketed. Records required under this proposed provision could include a copy of the relevant FDA approved warning plan, copies of the product labels maintained in the production records (see proposed § 1120.70(b)(6)), distribution records maintained under proposed § 1120.104(b), and any additional records demonstrating compliance with any requirements for random distribution and random and equal display.

The Agency has observed that many tobacco product manufacturers have adopted a number of different practices that would meet the requirements in proposed § 1120.98(b). For example, FDA is aware that some smokeless tobacco manufacturers keep records from audits or an accounting of each of the four required warning statements that are ordered for and applied to smokeless tobacco product packaging to confirm that over a 12-month period, each of the four required warning statements are randomly displayed, in as equal a number of times as is possible for each brand of product. FDA is aware that other manufacturers have used a quality audit, to verify the production of required warning statements on packaging within a 12-month period (Ref. 162). Other manufacturers document in their production, inventory, or shipment records the specific warning statements that have been used or applied to packaging, and demonstrate through distribution records that the required warning statements have been randomly distributed.

The industry GMP recommendations do not call for warning plans. The Agency believes that the proposed requirements would help assure that the public health is protected. This provision would help ensure that manufacturers who produce finished tobacco products that are subject to a warning plan establish and maintain packaging procedures to ensure compliance with applicable laws and regulations to warn users of known health risks. The World Health Organization (WHO)'s Framework Convention on Tobacco Control (FCTC), an evidence-based treaty, provides a regulatory strategy for health warnings on packaging and labeling (Ref. 163), for addressing the serious negative impacts of tobacco products, calls for rotating health warnings to ensure that they do not become stale (Ref. 164). Salient warnings would be more visible to consumers, informing them of the consequences associated with use of tobacco products. Accordingly, this provision would help assure that the public health goals of the warning label requirements are met.

These proposed requirements also would help assure that tobacco products are in compliance with chapter IX of the FD&C Act. Under section 903(a)(1) of the FD&C Act, a tobacco product is deemed to be misbranded if its labeling is false or misleading in any particular. This could include, for example, a case in which a manufacturer includes the same single warning on all product packages, when there is a requirement to rotate a number of different warnings (see section 201(n) of the FD&C Act). By ensuring that tobacco product manufacturers establish and maintain packaging procedures that address required warning plans, the proposed provision would help ensure that tobacco products are not misbranded.

G. Handling, Storage, and Distribution

1. Handling and Storage

Proposed § 1120.102 would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, the proposed handling and storage provision in the industry recommendations, and controls that are already being implemented by the tobacco industry, as observed by FDA during inspections.

Handling and storage procedures under proposed § 1120.102 could include, for example, establishing storage conditions to control temperature and humidity to prevent mold growth, and adopting certain product segregation practices to prevent mixups. If a manufacturer restricts access to designated storage areas through the use of keys, bar code readers, or other means, the procedures should detail, among other things, who is permitted access and what steps should be followed prior to handling. Such procedures are intended to prevent mixups or the use of unsuitable materials in manufacturing.

These proposed requirements would apply to all stages of handling and storage in which a manufacturer is involved, including handling and storage as part of the production process. The handling and storage procedures should complement other procedures required under this proposed rule, such as, for example, the procedures required in proposed Subpart C—Buildings, Facilities, and Equipment.

The proposed handling and storage requirements are intended, in part, to prevent deterioration of the tobacco product after it has undergone product acceptance activities and has been approved for release into distribution. For example, the tobacco-specific

nitrosamines (TSNAs) 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosonornicotine (NNN) are formed from tobacco alkaloids and nitrosating agents, such as nitrite (Ref. 165). These TSNAs are potent carcinogenic agents found in smokeless tobacco products (82 FR 8004, January 23, 2017). The concentration of NNK and NNN may increase in smokeless tobacco when stored at room temperature due to microbial action (Refs. 56 and 166). Additionally, high storage temperature of cured tobacco has been shown to contribute to TSNA formation (Ref. 167). However, controls exist that can limit the formation of TSNA, including refrigeration of the tobacco products during storage (Ref. 165). If such handling and storage conditions are necessary to ensure that a finished or bulk tobacco product remains within its NNN or NNK specification, this provision would require a manufacturer to establish and maintain procedures for such handling and storage controls.

The proposed handling and storage requirements are also intended to prevent contamination. For example, in storage, the environment's moisture content and relative humidity can support mold growth and aflatoxin production by aflatoxigenic molds (Refs. 168 and 169). Manufacturers can decrease the likelihood of mold contamination in tobacco products by controlling the temperature and humidity during storage. Additionally, FDA is aware that tobacco products in many countries contain numerous contaminant by-products attributed to storage practices (Ref. 165). These storage practices can introduce NTRMs, including manufacturing materials, pesticides, cleaning compounds, microorganisms, and animal or insect excrement or parts into the tobacco product (Refs. 6 and 170). A tobacco product can also become contaminated if it is stored close to highly aromatic liquids or materials, such as kerosene, oils, grease, and paraffin (Ref. 171). The proposed requirements in this section are intended to ensure that tobacco product manufacturers adopt handling and storage practices that prevent such contamination.

The proposed handling and storage requirements are also intended to protect against problems that could occur from product or ingredient mixups. For example, if the manufacturer does not implement these handling and storage requirements and ingredients are mishandled during the manufacturing process without detection, a label might not accurately reflect the content of ingredients of the product.

The Agency believes that the proposed handling and storage requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Establishing and maintaining procedures for handling and storage is an important step in preventing nonconforming products and mixups, contamination, deterioration, adulteration, and misbranding.

2. Distribution

Proposed § 1120.104 would require finished and bulk tobacco product manufacturers to establish and maintain procedures related to the distribution of finished and bulk tobacco products. These proposed requirements would apply only to tobacco product distribution within the manufacturer's control (*i.e.,* to the initial consignee and direct account). These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, the distribution provision in the industry recommendations, and practices that are already being implemented by the tobacco industry, as observed by FDA during inspections.

Specifically, proposed § 1120.104(a)(1) would require finished and bulk tobacco product manufacturers to establish and maintain distribution procedures to ensure that finished and bulk tobacco products are distributed to the initial consignee under appropriate conditions to prevent nonconforming product as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. FDA intends for this provision to provide manufacturers flexibility in determining what conditions are appropriate for protecting their tobacco products against mixups, deterioration, contamination, adulteration, or misbranding. For example, a tobacco product manufacturer could seek to ensure that distribution conditions are appropriate by inspecting the integrity of shipping containers to make sure that there are no problematic conditions such as holes or gaps, checking the cleanliness and environmental conditions of transport containers, and making sure that there are no conditions that can attract insects and rodents. Additionally, a tobacco product manufacturer could establish distribution requirements to prohibit the distribution of finished and bulk tobacco products in transport containers that ship agricultural products, such as livestock and manure remnants in the form of organic fertilizer, to prevent tobacco products from becoming contaminated with bacteria such as *E. coli* and fecal coliform (Ref. 172). A manufacturer could also establish shipping procedures that require inspection of the shipping conditions to prevent the shipment of tobacco product in circumstances where they may become contaminated by toxic or hazardous substances. For example, shipping procedures could address circumstances similar to a reported situation where a shipment of cigarettes was contaminated with ant and roach spray (Ref. 148).

Proposed § 1120.104(a)(2) would require finished and bulk tobacco product manufacturers to establish and maintain distribution procedures to ensure that only those finished and bulk tobacco products approved for release are distributed. (See proposed § 1120.70 for the proposed requirement for review and approval of the production record for release of each batch of finished and bulk tobacco product for distribution.) This requirement is intended to prevent the release of nonconforming product or products that have not undergone applicable product acceptance activities. Tobacco product manufacturers would have the flexibility to determine the appropriate procedures and practices to control the distribution of their tobacco products. For example, FDA has observed on inspections that tobacco product manufacturers have used printed or electronically scannable labels, tags, and signs to ensure that only tobacco products that have been approved for release may be distributed.

Proposed § 1120.104(b) would require finished and bulk tobacco product manufacturers to maintain distribution records. According to this paragraph, the distribution records would be required to include the name and address of the initial consignee, the identification and quantity of finished or bulk tobacco products shipped, date of shipment, and the manufacturing code(s) of the tobacco products. The meaning of ''consignee'' in this context would be the person to whom the tobacco product is delivered, which is consistent with the use of consignee in other Agency distribution recordkeeping requirements (*e.g.,* § 820.160). The initial consignee is the first person to whom the manufacturer (or any person(s) acting on behalf of the manufacturer) delivers the tobacco products. The initial consignee can be a warehouse, wholesaler, distributor, or retailer, who is a customer of the manufacturer. However, the requirement would not include

individual purchasers of tobacco products for personal consumption. This basic information is needed to identify where tobacco products have been initially distributed in order, for example, to facilitate a corrective action such as a recall or stock recovery.

Proposed § 1120.104(c) would require finished and bulk tobacco product manufacturers to maintain a list of direct accounts. For purposes of this rule, ''direct accounts'' means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the tobacco product manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

The list of direct accounts would be required to contain the name, address, and contact information of each entity. This list is different from the distribution record, which only lists the individual initial consignee associated with a particular shipment. The list of direct account information is necessary, for example, to facilitate investigations of nonconforming product. In addition, this information would assist in tracing finished or bulk tobacco products to all persons to whom the tobacco product manufacturer has distributed or sold products. This requirement would be consistent with 21 CFR part 7 provisions regarding voluntary recalls initiated by manufacturers.

The proposed distribution requirements would help assure that the public health is protected by requiring finished and bulk tobacco products to be distributed under appropriate conditions to prevent nonconforming tobacco products as well as mixups, deterioration, contamination, adulteration and misbranding of tobacco products. A finished or bulk tobacco product may deteriorate or be adversely affected by distribution conditions (*e.g.,* environmental transport conditions).

The proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by helping to establish traceability of finished and bulk tobacco products. Tracing finished and bulk tobacco products would enable tobacco product manufacturers and FDA to identify where tobacco products that do not meet the requirements of the FD&C Act have been distributed and sold. This information would facilitate notification of consignees and persons in the distribution chain in order to efficiently conduct a product recall under section 908 of the FD&C Act, if necessary. The scope of a product recall would likely be much broader than necessary if records of product distribution were not available to pinpoint distribution, thus potentially decreasing a recall's effectiveness and increasing cost to the tobacco product manufacturer.

The proposed requirements also, in conjunction with the proposed unique identifier, production record, and manufacturing code requirements, would help enable FDA to assure the integrity of the supply chain from suppliers to finished or bulk tobacco product manufacturers as well as from finished or bulk tobacco product manufacturers to the initial consignees.

H. Recordkeeping and Document Controls

Proposed § 1120.122 would establish recordkeeping and document control requirements.

For purposes of this proposed part 1120, documents generally refer to written (paper or electronic) procedures, forms, work instructions, etc., such as the procedures that a finished or bulk tobacco product manufacturer establishes and maintains to address a TPMP requirement. For example, a tobacco product complaint procedure and complaint form template that is established under proposed § 1120.14 are considered to be documents. For purposes of this proposed part 1120, records generally refer to the written (paper or electronic) output from activities undertaken to implement the documents. For example, records include written results of complaint and nonconforming product investigations, and laboratory testing activities. We note that this use of the term ''record'' is specific to proposed part 1120 and does not affect how that term is applied in other contexts.

All documents and records required under the proposed rule would be required to meet certain requirements under proposed § 1120.122(a). We are proposing additional requirements for records under proposed § 1120.122(b) and for documents under proposed § 1120.122(c). FDA notes that if a tobacco product manufacturer establishes and maintains documents and records required under proposed part 1120 in an electronic format, then they are subject to the requirements of 21 CFR part 11.

Specifically, proposed § 1120.122(a) would establish general requirements that apply to all documents and records required under proposed part 1120. Proposed § 1120.122(a)(1) would require that documents and records required under proposed part 1120 be written in English, or an accurate English translation must be made available upon request. Documents and records (including any associated source data) could be maintained in the native language of a foreign tobacco product manufacturer as long as a translation is made available upon request. FDA expects that a manufacturer would fulfill requests for documents or records translations promptly to ensure that there are no delays of inspections or investigations. The accuracy of the English translation could be demonstrated by, for example, providing a certification of the translation, using a certified translator, or providing information on the competency of the translator.

Proposed § 1120.122(a)(2) would require that all documents and records required by proposed part 1120, that are associated with a batch of finished or bulk tobacco product, must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Examples of such records include purchasing, acceptance, production, laboratory testing, warning plans, and distribution records. FDA has selected 4 years as a means to help assure that the records would be available for at least one biennial FDA inspection under sections 704 (21 U.S.C. 374) and 905(g) of the FD&C Act.

Documents and records that would be required by proposed part 1120, that are not associated with a batch of finished or bulk, would be required to be retained for a period of not less than 4 years from the date they were last in effect. Examples of these documents and records include training, calibration, and pest control procedures and records required under proposed §§ 1120.12 (Organization and personnel), 1120.36 (Equipment) and 1120.34 (Buildings, facilities, and grounds), respectively.

Proposed § 1120.122(a)(3) would require that all documents and records required under proposed part 1120 be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. FDA interprets ''readily accessible'' to FDA as the documents and records being made available to FDA upon request within the course of an inspection. Documents and records, regardless of location, would be considered readily accessible to FDA if the tobacco product manufacturer can respond to an FDA investigator's request promptly and

without delaying the inspection or investigation.

The requirement to maintain documents and records at the manufacturing establishment or other locations that are readily accessible to responsible officials of the tobacco product manufacturer is intended to enable the manufacturer to exercise control over the documents and records, which will help ensure accountability. FDA would consider ''responsible officials'' to include management with executive responsibility. The proposed requirement also would help ensure that the responsible officials at the manufacturing establishment have ready access to those documents and records that are essential for performing required activities and making critical decisions.

This provision would require that the documents and records required to be maintained, including those not stored at the establishment, be made readily accessible during the 4-year retention period to FDA for inspection and photocopying or other means of reproduction. Documents and records required under this part may be retained either as originals or as true copies such as photocopies, microfilm, microfiche or other reproductions which preserve the content and meaning of the data, including associated metadata and audit trails. Where reduction techniques are used, suitable reader, computer, and copying equipment should be readily accessible to FDA during an inspection. Documents and records that can be immediately retrieved from another location as originals or true copies, including by computer or other electronic means, would meet the requirements of this paragraph.

Proposed § 1120.122(b) would establish additional requirements that apply to all records required under proposed part 1120. Specifically, proposed § 1120.122(b) would require that all records, regardless of storage medium, must be attributable, legible, contemporaneously recorded, original, and accurate (ALCOA). The ALCOA requirements of proposed § 1120.122(b) are basic principles that describe minimum standards for how records should be collected and maintained in order to protect the integrity of the data they preserve. For purposes of this requirement, records include all records required to be maintained under proposed part 1120, such as, for example, written results from inspections, tests, other verification activities. These ALCOA requirements would apply to all records regardless of format or storage media, including paper-based and electronic records. For example, laboratory test records would be required to include all relevant raw data, graphs, and charts. This provision is intended to ensure the data integrity of information generated to demonstrate compliance with the proposed TPMP rule.

The ALCOA requirements are defined under proposed § 1120.122(b)(2) and further explained as follows:

- *Attributable* means that the data in a record is traceable to its source. This means it should be attributable to the originator of the data, whether that source is an individual, an automated piece of equipment, or individual operating equipment. For example, if an ENDS manufacturer conducts an acceptance test of e-liquid, using gas chromatography–mass spectrometry, to determine its nicotine concentration, the record would have to identify the gas chromatography-mass spectrometry equipment used and the personnel who performed the test and state the result. This applies to any changes, corrections, deletions, or revisions to a record.
- *Legible* means the record is permanently recorded in a readable format. A legible record prevents loss and preserves traceability of changes without obscuring the original entry or subsequent additions or deletions. For example, if test information is recorded on a laboratory notebook or form, it would have to be recorded in ink. If any changes are made, the original entry would have to be struck out to preserve the first capture of the data and initialed and dated for traceability. Electronic data that are first stored in temporary memory before creating a permanent record would not comply with the proposed requirement, because the process would fail to save the first capture of the data and would not preserve the traceability of changes. Practices like this, that allow data manipulation prior to transfer to the permanent record, compromise the data integrity of the record and would not comply with this requirement.
- *Contemporaneously recorded* means that data is recorded at the time the procedure, assessment, observation, or other activity is performed.
- *Original* means the record reflects the first capture of the data and all information related to all subsequent changes required to fully reconstruct the TPMP activities. An original record preserves the record content and the meaning of the data, including associated metadata. Original records may be static or dynamic. A static record, such as a paper record, is fixed and allows little or no interaction between the user and record content. Records in a dynamic state allow the user to interact with the information. For example, electronic records in database formats that allow the user to track, trend, and query data are examples of records in a dynamic state. This provision would require that information that is first captured in a dynamic state remain available in that state.
- *Accurate* means that the data in a record is correct, truthful, complete, valid, and reliable. All records required under this part, including the associated data and metadata, must be accurate. Depending on the manufacturing process and record systems used, data may be captured manually by human observation or automated electronic equipment (*e.g.,* an electronic manufacturing system, records, or laboratory system). If errors occur, they should be specifically noted. *Accurate* also would require that there are no changes or edits to the recorded data without documented amendments. Electronic data that are first stored in temporary memory before creating a permanent record would not comply with the proposed requirement because such practice allows for data manipulation prior to recording, thus compromising the data integrity.

In order to comply with proposed § 1120.122(b) and other requirements of this proposed rule, finished and bulk tobacco manufacturers would need to preserve the metadata associated with TPMP records. Metadata are the contextual information required to understand the data. For example, without metadata the number ''20'' is meaningless. With additional context such as the unit of measure (*e.g.,* 20 mg nicotine/cigarette), the value 20 is given meaning. Metadata are structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data. Metadata include the unit of measure, date/time stamp for when the data were acquired, identification of the person who conducted the test or analysis that generated the data, and identification of the equipment used to capture the data. Specific pieces of metadata may be required by other subparts of this proposed rule.

Finished and bulk tobacco product manufacturers also may find that audit trails assist them in demonstrating that information or data in a record complies with the proposed recordkeeping requirements. An audit trail is a form of metadata that contains information associated with actions related to the creation, modification, or deletion of a TPMP record. An audit trail is a chronology of the ''who, what, when, and why'' of a record. For a paper

record, the audit trail of a change would be recorded via a single line cross-out that allows the original entry to remain legible and includes the initials of the person making the change, the date of the change, and the reason for the change. The audit trail for a paper record should be contained within the four corners of the record. For electronic records, an audit trail is a secure, computer-generated, time-stamped electronic file that that allows for reconstruction of the course of events relating to the creation, modification, or deletion of a record.

Finished and bulk tobacco product manufacturers may comply with the proposed requirement of § 1120.122(b) that records be ''original'' by maintaining original records or true copies of those records through the records retention period. A true copy, like the original record, would preserve the record content and meaning of the data, including associated metadata and any audit trails. A true copy may only be retained in lieu of the original if it preserves the static or dynamic state of the original and if the copy has been compared to the original and verified to contain the entire content and meaning of the original record, including all metadata and any audit trails. Consistent with the cGMP requirements for other FDA-regulated products, true copies may be photocopies, pictures, scanned copies, microfilm, microfiche, electronic records, or other equivalent reproductions depending on form and content of the original record.

The extent of what would need to be included in a true copy is dependent on the original record. For example, when an individual writes a contemporaneous observation in a notebook or on a worksheet or scrap of paper, this is the first capture of data; this piece of paper would need to be retained unless a true copy is created. If a true copy is made, it must capture any written notes, strikeouts, erasure marks, and all other alterations to the original record.

Proposed § 1120.122(c) would require tobacco product manufacturers to establish and maintain procedures to control all documents established to meet requirements under proposed part 1120. For the purposes of proposed part 1120, documents generally refer to written procedures (such as standard operating procedures), work instructions, and blank forms, such as the procedures that a finished and or bulk tobacco product manufacturer establishes and maintains to address a TPMP requirement. However, completed forms and testing results generated when implementing activities under proposed part 1120 are considered records and therefore would not be subject to § 1120.122(c). For example, a pH acceptance testing procedure and blank form to record the pH test result are documents that would be subject to the general requirements under § 1120.122(a) and to the document controls under proposed § 1120.122(c). When pH testing is performed according to the testing procedure and the results are recorded on the form, this creates a record subject to the requirements under proposed § 1120.122(a) and (b). Similarly, a complaint procedure and a complaint record template established to comply with proposed § 1120.14 are documents and would need to comply with the proposed requirements in § 1120.122(a) and (c); the record maintained for a specific complaint event would be required to comply with the proposed requirements in § 1120.122(a) and (b), but it would not be required to comply with the proposed requirements in § 1120.122(c).

Proposed § 1120.122(c)(1) would require the document control procedures to include requirements for document approval and distribution. To comply with this proposed provision, manufacturers would need to assign personnel to review and approve all documents established to meet the requirements of proposed part 1120. Such review and approval would have to be completed before the document is implemented. For example, under proposed § 1120.14, manufacturers would be required to establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all complaints. Personnel must review and approve the complaint procedure prior to the issuance and use of the procedure. The approval would be required to include the date, name, and signature of the individual(s) approving the document. Documents that are established to meet requirements proposed part 1120 would be required to be available at all locations for which they are designated, used, or otherwise necessary, and all such documents that are superseded and obsolete would have to be promptly removed from all points of use or otherwise prevented from unintended use. On inspections, FDA has observed the use of obsolete documents on the production line. Personnel who use an obsolete document may not adequately perform a required activity, which can result in the manufacture of nonconforming products.

Proposed § 1120.122(c)(2) would require that the document control procedures include requirements related to document changes. Specifically, changes to documents would have to be reviewed and approved prior to implementation by an individual(s) in the same function or part of the organization (*e.g.,* Quality Assurance Department) that performed the original review and approval. The purpose of this proposed requirement is to ensure that individual(s) in the same job function as those who originally reviewed and approved the document review any changes because these individuals typically have the best insight on the impact of the changes.

Proposed § 1120.122(c)(2) also would require that approved changes be communicated to the appropriate personnel in a timely manner. For example, a manufacturer could comply with this requirement by making the changed documents readily accessible at all locations for which they are designated, used, or otherwise necessary, and by retraining affected personnel on the changed documents. FDA has observed on inspections instances where manufacturers made changes to procedures, but the changes were not communicated in a timely manner to the personnel utilizing the documents. Without these proposed requirements in place, personnel may not be aware that changes have been made to a procedure, which can result in the manufacture of nonconforming products.

In addition, proposed § 1120.122(c)(2) would require that superseded and obsolete documents be archived. For purposes of proposed part 1120, archiving means that the superseded or obsolete document would be retained for historical reference. These documents would have to be retained in accordance with the time period in proposed § 1120.122(a)(2) (*e.g.,* for 4 years after last use, when not associated with a batch of finished or bulk tobacco product). These documents may be useful to manufacturers when performing an investigation of products manufactured and distributed using a previous version of a document. For example, an obsolete MMR would provide helpful information on specifications when investigating a nonconforming product that was manufactured under that version of the MMR.

Further, proposed § 1120.12(c)(2) would require tobacco product manufacturers to maintain records of changes to documents. According to this paragraph, document change records must include the following information: a description of the change; identification of the affected documents; the name and signature of the approving individual(s); the approval date; and the

date the change becomes effective. Maintaining change records on computers would be acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures. Electronic signatures could be used to satisfy this requirement. All electronic records are subject to part 11.

The proposed requirements would help assure that the public health is protected. Documents and records are essential to the ability to conduct adequate investigations in case of problems (*e.g.,* to determine the scope and cause of a nonconforming product issue) and take an appropriate corrective action, such as a recall.

The Agency also believes that the proposed document control requirements would help assure that the public health is protected. Document controls would establish a formal, documented system that defines how and by whom documents will be reviewed and approved. They also would include the procedures used for updating documents, for the distribution and maintenance of all required documents, and for the removal of obsolete and superseded documents. Controlled documents are necessary to establish consistent practices in manufacturing operations and provide a basis for employee training and supervision. If documents are not appropriately approved and current versions distributed for use, or if obsolete documents are used to manufacture tobacco products, manufacturing operations might proceed in an ad hoc manner that could result in the manufacture of nonconforming products. For example, if a manufacturer changes an acceptance activity procedure document to include a visual inspection of a new type of foreign material to address consumers' complaints, this change would have to be reviewed, approved, and communicated to the appropriate personnel in a timely manner. If personnel who are responsible for conducting this visual inspection are not informed of this change, they may fail to perform this activity and release products that contain this foreign material.

The proposed requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by ensuring that FDA can verify that the activities required under proposed part 1120 have been implemented and that the documents and records are trustworthy and reliable. Data integrity is an essential foundation of the proposed rule and is critical to FDA's ability to protect the public health. The proposed ALCOA requirements are necessary in order to protect the integrity of TPMP records. Widely accepted, the ALCOA requirements are the basic principles of data integrity (Refs. 174–177). The effectiveness of FDA inspections depends on the veracity of the information provided by regulated entities to the Agency. The vast majority of the time, FDA is absent from the establishment. The Agency depends on records and documents to reconstruct events which it was not present to witness. FDA's experiences in other regulated product areas have shown that data-integrity-related manufacturing violations, including data fraud and falsification of records, have led to numerous regulatory actions. Other regulatory agencies and public health organizations, like the World Health Organization, the European Medicines Agency, the Medicines & Healthcare Products Regulatory Agency of the United Kingdom, and the Therapeutic Goods Administration of Australia share FDA's view that data integrity principles are a core component of good manufacturing practice (id.). Because data integrity principles are essential to the quality systems and QMS, they are among the portions of those approaches adopted by the Agency in this proposed rule. Data integrity lapses in the regulated manufacturing environments are critical deficiencies because they undermine the ability of FDA to verify if a product is manufactured in accordance with its marketing authorization. Consequently, the proposed ALCOA requirement helps assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by giving the Agency confidence in the integrity of the records which are at the center of the regulatory scheme envisioned by the Tobacco Control Act.

In addition, the Agency believes that the proposed document control requirements would help ensure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act, because, for example, documents established to meet the requirements of proposed part 1120 are necessary to implement the manufacturing methods and procedures specified in the MMR and ensure that a tobacco product conforms to its specifications. Thus, these documents would enable FDA to help ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics.

I. Small Tobacco Product Manufacturers

Proposed § 1120.130 provides for an extended compliance deadline that would grant small tobacco product manufacturers of finished and bulk tobacco products additional time to implement the requirements in part 1120, consistent with section 906(e)(1)(B)(v) of the FD&C Act. Instead of being required to comply with part 1120 on the effective date of the final rule, small tobacco manufacturers would be required to comply with the requirements in part 1120 4 years after the effective date of the final rule. FDA believes that this extended compliance deadline for small tobacco product manufacturers would provide them with sufficient time to implement the proposed requirements.

J. Exemptions and Variances

1. Exemptions and Variances

Proposed § 1120.140 explains that, under section 906(e)(2) of the FD&C Act, any person subject to any of the TPMP requirements could petition FDA for a permanent or temporary exemption or variance from any of these requirements. The petitioner remains subject to the relevant requirements unless FDA grants the petition for an exemption or variance under proposed § 1120.146. Thus, any person who petitions FDA for an exemption or variance would have to follow the TPMP requirements in proposed part 1120 unless and until FDA grants the petition.

Section 906(e)(2)(A) of the FD&C Act provides FDA the authority to prescribe the form and manner for submission of petitions. Under proposed § 1120.140, an individual petitioning for an exemption or variance would have to submit the petition, including all information supporting the petition, in an electronic format that FDA can process, review, and archive. FDA intends to provide information on its website on how to provide the electronic submission to FDA (*e.g.,* information on electronic media and methods of transmission). Electronic submission of information is consistent with the Government Paperwork Elimination Act (Pub. L. 105–277, Title VII). Because of the broad availability of the internet, FDA does not anticipate any need to submit a petition for an exemption or variance, and supporting materials, in a nonelectronic format. However, if the petitioner is unable to submit a petition in an electronic

format, the petitioner may submit a written request to FDA asking that FDA allow the submission in an alternative format, explaining in detail why the petitioner cannot submit the petition in an electronic format and why an alternate format is necessary. Proposed § 1120.140 would also require that all petitions, including supporting information, and all requests to submit a petition in an alternative format, be legible and in the English language. These proposed requirements would ensure that FDA could review the petitions expeditiously and appropriately.

2. Petition for an Exemption or Variance

Proposed § 1120.142 would require that a petition for an exemption or variance be submitted with supporting documentation and contain: (1) the petitioner's name, address, and contact information; (2) identification of the tobacco product(s); (3) the requirement(s) in part 1120 for which an exemption or variance is requested; a detailed explanation of why the exemption or variance is requested, including why the tobacco product manufacturer is not able to comply with the requirement(s) of proposed part 1120; and (4) the duration of the proposed exemption or variance. In addition, for a petition for a variance, this section would require a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement(s) in part 1120, as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health will be protected and that the tobacco product(s) will be in compliance with chapter IX of the FD&C Act. For a petition for an exemption, this provision would require a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement(s) is not required to assure that the public health will be protected and the tobacco product will be in compliance with chapter IX of the FD&C Act. Additional information that would be required with a petition for an exemption or a petition for a variance includes: any other information justifying the exemption or variance; a statement certifying that, to the best of the petitioner's knowledge and belief, the information provided in the petition includes all information and views on which the petition relies, including representative data, and any information known to the petitioner that is unfavorable to the petition; and an environmental assessment (EA) under part 25 (21 CFR part 25) prepared in accordance with § 25.40.

FDA expects that the submission of this information, along with supporting documentation will enable FDA to determine whether to grant a petition for a variance or exemption. FDA is considering including additional requirements for the specific contents of petitions for variances and exemptions and is seeking comment on the kinds of information and/or evidence that would be helpful in determining whether a petition should be granted.

3. Referral to the Tobacco Products Scientific Advisory Committee (TPSAC)

Proposed § 1120.144 explains that FDA may refer any petition submitted under this subpart to the TPSAC. If FDA refers a petition for an exemption or variance to the TPSAC, the TPSAC would be required to report its recommendations to FDA with respect to the petition referred to it within 60 days after the date of the petition's referral.

4. Petition Determination

Proposed § 1120.146(a) explains how FDA would make a determination on a petition for an exemption. Under proposed § 1120.146(a)(1), the Agency may, upon review of the information submitted and any recommendation from the TPSAC, approve a petition for an exemption from a TPMP requirement if it determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with chapter IX of the FD&C Act. As discussed above, in deciding whether to grant or deny a petition FDA will consider all the information provided by the petitioner including the basis of the petitioner's determination that compliance with the requirement is not needed to assure that the public health is protected. Proposed § 1120.146(a)(2) provides that, if FDA determines that the information submitted by the petitioner is insufficient to enable FDA to make a determination whether an exemption is appropriate, the Agency could request additional information from the petitioner. Proposed § 1120.146(a)(2) also provides that if the petitioner fails to respond by the time specified in the request, FDA could consider the exemption request withdrawn. FDA specifically requests comments from stakeholders as to what information should be included in a petition for exemption and how long it would take for a typical firm to gather and prepare the information that would be included in the petition for exemption.

Proposed § 1120.146(b) explains how FDA would make a determination on a petition for a variance. Under proposed § 1120.146(b)(1), the Agency may, upon review of the information submitted and any recommendation from the TPSAC, approve a petition for a variance if it determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirements in part 1120 are sufficient to assure that the tobacco product will be in compliance with chapter IX of the FD&C Act. As discussed above, in deciding whether to grant or deny a petition FDA will consider all the information provided by the petitioner, including the basis of the petitioner's determination that the proposed alternative methods, facilities, and controls are sufficient to assure that the public health is protected. Proposed § 1120.146(b)(2) provides that, if FDA determines that the information submitted by the petitioner is insufficient to enable FDA to make a determination whether a variance is appropriate, the Agency may request additional information from the petitioner. Proposed § 1120.146(b)(2) also provides that if the petitioner fails to respond by the time specified in the request, FDA may consider the variance request withdrawn.

Proposed § 1120.146(c) explains the timeframe in which FDA would make a decision on a petition. Proposed § 1120.146(c) provides that FDA would either grant or deny a petition within 60 days after the date the complete petition was submitted to FDA under § 1120.142 or within 60 days after the day after FDA referred the petition to TPSAC under § 1120.144, whichever date is later. The 60-day review period under proposed § 1120.146(c)(1) would begin when FDA receives a complete petition. Thus, if FDA receives an incomplete petition and requests additional information under § 1120.146(a)(2) or § 1120.146(b)(2), the 60-day review period would not begin until FDA receives the additional information that completes the petition. FDA intends to request additional information, if necessary, within 60 days after the date the incomplete petition was submitted to FDA.

Proposed § 1120.146(d) provides that an order from FDA granting a variance would prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product as may be necessary to assure that the tobacco product will be

in compliance with chapter IX of the FD&C Act.

5. Hearing

Proposed § 1120.148 explains that after FDA issues an order under § 1120.146, the petitioner would have the opportunity for an informal hearing under part 16 (21 CFR part 16).

V. Proposed Effective and Compliance Dates

FDA proposes that any final rule become effective 2 years after the date the final rule publishes in the **Federal Register**. Section 906(e)(1)(B)(iv) of the FD&C Act specifies that, in establishing the effective date of any TPMP regulations, FDA must take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and must provide for a reasonable period of time for such manufacturers to conform to any TPMP regulations. FDA has considered these factors in determining the proposed effective dates for this rule.

The Agency's proposed rule utilizes a standards-based approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Thus, the proposed regulation provides the framework that all manufacturers would utilize and apply in a manner that is appropriate to a given tobacco product. FDA is proposing this effective date to ensure that manufacturers of all types of covered tobacco products will have adequate time to comply regardless of the complexity of their manufacturing process.

In addition, FDA inspections have demonstrated that a number of manufacturers already have implemented many measures similar to the proposed TPMP requirements. FDA also believes that manufacturers other than small tobacco product manufacturers have the financial resources to comply with the proposed requirements within 2 years, as demonstrated by the proposed regulatory impact analysis (PRIA) and the fact that a number of manufacturers already have implemented similar provisions. Those manufacturers meeting the definition of small tobacco product manufacturers will have an additional 4 years to come into compliance (see proposed § 1120.130). FDA inspections and facility visits have noted that entities that manufacture the originally regulated products (*i.e.,* cigarettes, smokeless, cigarette tobacco, and RYO) as well as entities that manufacture deemed products generally already have some manufacturing controls in place that are similar to the proposed rule (*e.g.,* a QMS or some portions of a QMS). FDA believes that the proposed effective date is feasible and that different effective dates for different types of manufacturers are not needed.

Accordingly, FDA believes that 2 years is a reasonable period of time for manufacturers (other than small tobacco product manufacturers) to comply with any final TPMP regulations. During those 2 years, FDA expects that manufacturers would take steps to plan and implement business operations that will comply with the final rule. FDA specifically requests comment regarding this proposed 2-year effective date.

Section 906(e)(1)(B)(v) of the FD&C Act specifies that FDA may not require any small tobacco product manufacturer to comply with any TPMP regulations for at least 4 years following the effective date of the regulation. As discussed in subpart J of the proposed regulation, FDA proposes that small tobacco product manufacturers of finished and bulk tobacco products not be required to comply with the TPMP regulations until 4 years after the effective date of the final rule. This proposed compliance date would give small tobacco product manufacturers a total of 6 years to comply with the TPMP regulations, and FDA believes that this extended compliance date for small tobacco product manufacturers would provide them with sufficient time to implement the requirements in any final rule. This proposed effective date is consistent with the recommendation of some tobacco companies (Docket No. FDA–2013–N–0227). FDA requests comment on this proposed effective and compliance dates from all interested parties.

VI. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O. 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities are likely to incur a large portion of the costs to comply with the proposed rule, we find that the proposed rule would have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packing, and storage of tobacco products. The TPMP requirements described in the proposed rule are expected to ensure that tobacco product manufacturers control the design and specifications of finished and bulk tobacco products, providing a level of assurance of conformity in the production of tobacco products to established and required specifications that does not occur in the existing market for tobacco products, to prevent the adulteration and misbranding of finished and bulk tobacco products, and establish controls for traceability purposes.

We quantify two potential benefits of the proposed rule. First, the manufacturing controls required by the proposed regulation are likely to reduce the likelihood that nonconforming products are manufactured and commercially distributed which, in turn, would reduce social costs associated with product recalls and market withdrawals. The social costs of a recall, due to inadequate or

insufficient controls, may extend beyond the costs to the manufacturer conducting the recall and may include shareholders as well as consumers, retailers, and wholesalers. If a recall or market withdrawal were necessary, the records required by the proposed regulation would help locate nonconforming products that were commercially distributed, which would also be expected to reduce the cost of conducting recalls and market withdrawals, both voluntary and involuntary. Since 2009, tobacco product manufacturers have initiated eight voluntary recalls, resulting in at least three million cans of smokeless tobacco and 62 million cigarettes recalled or withdrawn from the market. Furthermore, we estimate that, if the proposed rule is finalized, the costs of product recalls and market withdrawals may fall by between $4 million and $213 million per year.

Another quantified potential benefit of the proposed rule is that adverse events due to nonconforming finished and bulk tobacco products would decrease as a result of improvements in the control of tobacco product manufacturing operations. We use data on exposure calls to Poison Control Centers (PCs) throughout the United States to quantify the impact of the proposed rule on the number of exposure calls reporting clinical effects such as vomiting, nausea, abdominal pain, etc. associated with the consumption of tobacco products that, according to the PCs Certified Specialists in Poison Information, had been tampered with or contaminated. We estimate from 2001 to 2030, a total of 11,135 projected exposures, or an annual average of 371 exposures per year, associated with the consumption of such products.[6] Based just on these data regarding calls to PCs, if the proposed rule is finalized, we estimate that the total (undiscounted) monetized health losses associated with contaminated tobacco products may be reduced by between $908 and $2,723 per year.

There are other potential benefits associated with the proposed rule which we have not quantified. First, the proposed recordkeeping provisions will also support FDA's regulatory compliance activities and help FDA implement and enforce other provisions of the FD&C Act which will likely generate government cost savings. Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in the quantified benefits. Third, the proposed rule's risk assessment, CAPA, tobacco products complaints and related provisions will facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. Other benefits include avoided spillover costs to capital markets.[7]

The potential costs of the rule include tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. Examples of these tasks include conducting new or more stringent manufacturing activities, writing and updating standard operating procedures (SOPs), training employees to engage in new or more stringent manufacturing activities, and keeping new or additional records. We estimate that (undiscounted) one-time costs range from $39 million to $73 million and (undiscounted) recurring costs range from $15 million per year to $56 million per year. FDA is also proposing that any final rule become effective two years after the date of the final rule's publication. FDA is further proposing in § 1120.130 of this rule that manufacturers meeting the definition of small tobacco product manufacturer would be required to comply with the requirements of this rule four years after the effective date of the final rule (*i.e.,* six years after the date of the final rule's publication). Because small manufacturers would have more time than non-small manufacturers to comply with the requirements of this proposed rule, we estimate all costs to reflect the staggered compliance dates. We estimate learning costs for both non-small and small manufacturers to begin one year after publication (year 1). Non-small manufacturers and small manufacturers would incur costs one and five years, respectively, after the publication date of a final rule as they work to come into compliance with the rule two and six years from the date of final publication.[8] We therefore estimate the present value of total domestic costs annualized over ten years using a discount rate of seven percent is estimated to range from $13 million per year to $54 million per year, and from $14 million per year to $43 million per year using a discount rate of three percent. Our estimated benefits will begin to accrue on the same years as the compliance dates (years 2 and 6). The present value of total benefits annualized over ten years using a discount rate of seven percent is estimated to range from $1.9 million per year to $97.0 million per year, and from $2.1 million per year to $106.5 million per year using a discount rate of three percent. Table 1 summarizes our estimate of the annualized costs and benefits of the proposed rule.

[6] The 11,135 projected exposures are estimated from observed 2001–2017 exposures (adjusted for under-reporting) and adjusted to account for apparent trend of increasing exposure calls from 2018 through 2030. We used this forecast to estimate a baseline trend of what would occur without implementing this proposed rule. Figures are also adjusted for underreporting as explained in the Benefits of the Proposed Rule, section D.2 of the Preliminary Regulatory Impact Analysis (Ref. 184).

[7] Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated quantified benefits do not include avoided spillover costs to capital markets.

[8] The year of publication is year zero and the effective date is year two. In order for non-small manufacturers to comply with the requirements of this rule by the effective date (year two), we assume they will begin to incur compliance costs on year one. For small manufacturers to comply four years after the effective date or year six, we assume they will begin to incur compliance costs on year five. Benefits from non-small and small manufacturers begin to accrue on year two and year six respectively. All values have been adjusted to reflect 2020 dollars. Estimated costs in Table 1 represent estimated costs incurred by domestic manufacturers and domestic importers. Estimated benefits in Table 1 are from reduced exposure and reduced recall related costs associated with both domestic and imported tobacco products sold in the U.S.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[$ millions/year]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year.	$27.2 29.9	$1.9 2.1	$97.0 106.5	2020 2020	7 3	10 10	Quantified benefits include a summation of potential reductions in (1) cost of recalls and market withdrawals and (2) adverse health effects associated with contaminated or otherwise nonconforming tobacco products.
Annualized Quantified					7 3	10 10	
Qualitative	Non-quantified benefits include (1) Government costs savings due to aiding FDA compliance efforts; (2) potentially reducing losses to health and property for users and nonusers associated with nonconforming tobacco products; and (3) facilitating the investigation and identification of causes and root causes of consumer complaints and other reports of adverse events.					10	
Costs:							
Annualized Monetized $millions/year.	27.0 28.2	13.3 13.7	41.1 43.0	2020 2020	7 3	10 10	Annualized total costs of compliance with the proposed rule. Range of estimates captures uncertainty.
Annualized Quantified					7 3	10 10	
Qualitative						10	
Transfers:							
Federal Annualized Monetized $millions/year.					7 3	10 10	
From/To	From:			To:		10	
Other Annualized Monetized $millions/year.					7 3	10 10	
From/To	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
One-time costs per small entity are between 0.06% and 0.11% of their average annual revenue. Due to many missing values from Census data, average small-entity impacts are likely subject to large variability, due to the significant amount of heterogeneity in small-entity impacts across entities of different sizes (See Ref. 184).
Wages:
Growth:

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (as Ref. 184) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements for Tobacco Product Manufacturing Practice.

Description: The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(b) of the Tobacco Control Act amends the FD&C Act by adding new chapter IX, which provides FDA with authorities to regulate tobacco products and imposes certain obligations on tobacco product manufacturers, retailers, and importers. Among the amendments are provisions that relate to tobacco product manufacturing practice requirements. The proposed provisions include, among other things, the authority to issue regulations relating to good manufacturing practice requirements; hereinafter TPMP, in order to assure that the public health is protected and

tobacco products are in compliance with the requirements of the FD&C Act.

Description of Respondents: This proposed rule applies to manufacturers (foreign and domestic) of finished and bulk tobacco products. Finished tobacco products include tobacco products, including all components and parts, sealed in final packaging (*e.g.,* rolling papers, filters, filter tubes, or e-liquids sold to consumers. Bulk tobacco products are tobacco products that are not sealed in final packaging but otherwise suitable for consumer use as tobacco products (*e.g.,* bulk cigarettes, bulk filters, bulk e-liquids).

Subpart B prescribes the proposed requirements pertaining to finished and bulk tobacco product manufacturers' management systems that cover a manufacturer's organization and personnel (§ 1120.12), tobacco product complaints (§ 1120.14), and CAPA (§ 1120.16).

Proposed § 1120.12 would require manufacturers to establish and maintain an organizational structure; have sufficient personnel to carry out the requirements under part 1120; designate, in writing, appropriate responsibility for all personnel who perform an activity subject to part 1120 and designate, in writing, management with executive responsibility who have the duty, power, and responsibility to implement the requirements under part 1120; establish and maintain training procedures; and maintain records of personnel qualifications and training records. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.14 would require manufacturers to establish and maintain procedures to receive, evaluate, investigate, and document complaints. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.16 would require manufacturers to establish and maintain procedures for implementing CAPA. These procedures are to require review of various sources of data for identifying and investigating existing and potential causes of nonconformities and design problems, acting to correct and prevent nonconformities and design problems, verifying or validating the CAPAs, implementing and documenting the changes needed, and communicating that information to specified personnel. Manufacturers must maintain records of all activities conducted under this section. Manufacturers would be required to keep records of all activities required under this provision.

Subpart C prescribes the proposed requirements that are specific to personnel practices (§ 1120.32), building, facilities, and grounds (§ 1120.34), equipment (§ 1120.36), and environmental controls (§ 1120.38).

Proposed § 1120.32 would require manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel, which must include requirements to ensure that contact between personnel and the tobacco product or environment would not result in contamination of the tobacco product.

Proposed § 1120.34 would require manufacturers to ensure each building, facility, and grounds is maintained in appropriate condition to prevent contamination and ensure that buildings and facilities are of suitable construction, design, and location to facilitate sanitation, maintenance, and proper operation. The provision also would require controls for water quality, and record keeping, as well as require manufacturers to establish and maintain procedures for cleaning and sanitation and animal and pest control. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.36 would require manufacturers to ensure that equipment used in manufacturing operations is appropriately designed, constructed, and suitable for its intended purpose, and must establish and maintain procedures for the routine cleaning and maintenance of equipment, as well as for the routine calibration of testing, monitoring, and measuring equipment to ensure proper performance. The provision also would require identification of major equipment and all processing lines. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.38 would require manufacturers to establish and maintain procedures to adequately control environmental conditions, where appropriate, and maintain and monitor environmental control systems to verify that the environmental controls are adequate and functioning properly. Manufacturers would be required to keep records of all activities required under this provision.

Subpart D of the proposed rule prescribes the requirements for design and development activities (§ 1120.42) and MMRs (§ 1120.44).

Proposed § 1120.42 would require manufacturers to establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. To control for risks, manufacturers would be required to conduct a risk assessment: (1) risk identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, production process, packing, and storage, including risks normally associated with the use of the tobacco product; (2) risk analysis of the nature and level of risk for each identified known or reasonably foreseeable risk; and (3) risk evaluation of each identified risk to determine the significance of the risk and the type of risk treatment needed. In addition, manufacturers would be required to perform risk treatment to significantly minimize or prevent risks identified that are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or that the manufacturer determines constitutes an unacceptable level of risk as well as to address risks for any applicable tobacco product standards to ensure that the tobacco product will conform to the specifications and requirements established in the tobacco product standard. Finally, manufacturers would be required to conduct a risk reassessment whenever the manufacturer becomes aware of new information that could change the risks assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures. Manufacturers would maintain records of all activities required under this section.

Proposed § 1120.44 would require that manufacturers establish and maintain an MMR for each tobacco product manufactured. Manufacturers would also establish and maintain procedures for the review and approval of the MMR.

Subpart E of the proposed rule prescribes the proposed requirements for purchasing controls (§ 1120.62), acceptance activities (§ 1120.64), production and process controls (§ 1120.66), laboratory controls (§ 1120.68), production records (§ 1120.70), sampling (§ 1120.72), nonconforming tobacco products (§ 1120.74), returned tobacco products (§ 1120.76), and reprocessing and rework (§ 1120.78).

Proposed § 1120.62 would require manufacturers to establish and maintain purchasing procedures, purchasing records, and procedures for qualifying its suppliers. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.64 would require manufacturers to establish and maintain procedures for acceptance activities

including inspections, evaluations, tests, and other verification methods manufacturers use in the manufacturing process. The written procedures would also be required to contain procedures and records for ensuring that each accepted incoming tobacco product is designated by a unique identifier, which must be maintained throughout the manufacturing process and documented in the production record.

Proposed § 1120.66 would require manufacturers to establish and maintain production procedures that describe the process specifications and process controls used in the manufacturing of tobacco products. Process controls include monitoring and acceptance activities such as inspection, testing, evaluation, or other verification activities. The procedures should also address removal of manufacturing material if it could reasonably be expected to have an adverse effect on the product, if applicable; changes to a production process; and process validation procedures to demonstrate that the process will be maintained in a state of control to ensure that tobacco products conform to their established specifications and other requirements when it cannot be fully verified that tobacco product specifications conform to the MMR. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.68 would require manufacturers to establish and maintain procedures for any laboratory controls employed to satisfy requirements in the proposed rule. The procedures include scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose, sampling plans that comply with § 1120.72 of the proposed rule, and demonstration of analytical control. Manufacturers would also be required to demonstrate the laboratory's competence to perform laboratory activities associated with the manufacture of finished or bulk tobacco products. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.70 would require manufacturers to establish and maintain procedures for the preparation of a production record for each manufactured tobacco product batch.

Proposed § 1120.72 would require manufacturers to have an adequate sampling plan using representative samples.

Proposed § 1120.74 would require manufacturers to establish and maintain procedures for the control and disposition of nonconforming tobacco products. These procedures include: (1) identification and segregation of potential nonconforming products; (2) investigation of all potential nonconforming products, including determination of the scope and cause of the nonconformance and the risk of illness or injury posed by the nonconformance; and (3) disposition and followup. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.76 would require manufacturers to establish and maintain procedures for the control and disposition of returned products. These procedures must address identification, segregation, evaluation, and disposition of returned products. Returned products must be segregated in a manner that prevents mix-ups and use of returned products prior to evaluation and disposition. Returned product must be evaluated to determine its disposition. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.78 would require manufacturers to establish and maintain procedures for reprocessing and reworking tobacco products. These procedures would require evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual; and must include the production processes, including process controls, and acceptance activities, used to ensure the reprocessed or reworked tobacco product conforms to the requirements established in the MMR for the subsequently manufactured tobacco product. Manufacturers would be required to maintain records of all activities required under this provision.

Subpart F of the proposed rule prescribes the proposed requirements for packaging and labeling activities (§ 1120.92), repackaging and relabeling activities (§ 1120.94), manufacturing codes on the packaging or label of tobacco products (§ 1120.96), and warning plans for packaging (§ 1120.98).

Proposed § 1120.92 would require manufacturers to establish and maintain procedures to control packaging and labeling activities. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.94 would require manufacturers to establish and maintain procedures to control repackaging and relabeling activities for those establishments engaging in such activities. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.96 would require manufacturers to apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.98 would require finished tobacco product manufacturers, who are required to comply with a warning plan for tobacco product packaging, to establish and maintain procedures to implement the requirements of such warning plan. Manufacturers would be required to keep records of all activities required under this provision.

Subpart G of the proposed rule prescribes the proposed requirements for activities associated with handling and storage (§ 1120.102) and distribution (§ 1120.104).

Proposed § 1120.102 would require tobacco product manufacturers to establish and maintain procedures for the handling and storage of tobacco products.

Proposed § 1120.104 would require tobacco product manufacturers to establish and maintain procedures for the distribution of finished and bulk tobacco products and to keep distribution records and records of direct accounts.

Proposed subpart H of the proposed rule prescribes the proposed general recordkeeping and document control requirements (§ 1120.122).

Proposed § 1120.122(a) would establish general requirements that apply to all documents and records required under proposed part 1120. Proposed § 1120.122(a)(1) would require that documents and records required under proposed part 1120 be written in English, or an accurate English translation must be made available upon request. All documents and records required by proposed part 1120, that are associated with a batch of finished or bulk tobacco product, must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records not associated with a batch must be retained for not less than 4 years from the date they were last in effect. Furthermore, all documents and records required under proposed part 1120 be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. FDA interprets ''readily accessible'' to FDA as the documents and records being made available to FDA upon request within the course of an inspection.

Proposed § 1120.122(b) would require that records required under the proposed rule are attributable, legible, contemporaneously recorded, original, and accurate. Proposed § 1120.122(c) would require tobacco product manufacturers to establish and maintain procedures to control all documents established to meet the requirements under proposed part 1120.

As required by section 906(e)(2) of the FD&C Act, subpart J of the proposed rule sets forth the procedures and requirements for petitioning for an exemption or variance from a TPMP requirement.

Proposed § 1120.140 explains that, under section 906(e)(2) of the FD&C Act, any person subject to any requirement of the TPMP regulations may petition FDA for a permanent or temporary exemption or variance from such requirement. The requirements under this part remain in effect unless FDA grants the petition for an exemption or variance under § 1120.146. Thus, any person who petitions FDA for an exemption or variance must follow the TPMP regulations while the petition is being considered and until FDA grants the petition. Under proposed § 1120.140, an individual petitioning for an exemption or variance must submit all information supporting the petition in an electronic form that FDA can process, review, and archive. Because of the broad availability of the internet, FDA does not anticipate any need to submit a petition for an exemption or variance and supporting materials in a non-electronic format. However, if the petitioner is unable to submit a petition in an electronic format, the petitioner may submit a written request to FDA requesting that FDA allow the submission in an alternative format and explain in detail why the petitioner cannot submit the petition in an electronic format.

Proposed § 1120.142 would require that a petition for an exemption or variance contain: (1) the petitioner's name, address, and contact information; (2) identification of the tobacco product; (3) the requirement in this part for which an exemption or variance is requested; (4) a detailed explanation of why the exemption or variance is requested; the duration of the proposed exemption or variance; (5) a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement in this part as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health is protected and the tobacco product(s) will be in compliance with chapter IX of the FD&C Act (for a petition for a variance); (6) a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the public health is protected and that the tobacco product will be in compliance with chapter IX of the FD&C Act (for a petition for exemption); (7) any other information justifying the exemption or variance; a statement certifying that, to the best of the petitioner's knowledge and belief, the petition includes all information and views on which the petition relies including representative data and information known to the petitioner which are unfavorable to the petition; and (8) an EA under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

FDA recognizes that many of the proposed provisions of the proposed rule are consistent with quality control and manufacturing practices that have already been voluntarily adopted by manufacturers. As a part of usual and customary business practices, FDA expects some baseline level of manufacturer compliance with the provisions of the proposed rule.

FDA's burden estimates are based on the PRIA, FDA inspection reports, estimates of the number of deemed tobacco product manufacturers published in the Deeming Rule (part 1143), and 2017 data on permits issued to tobacco manufacturers by the Alcohol and Tobacco Tax and Trade Bureau. The requirements in the proposed rule would apply to both domestic and foreign manufacturers of finished and bulk tobacco products.

As discussed in the PRIA, we estimate the number of affected entities, by major tobacco product group and size of operation group. We estimate that there is a total of 1,935 domestic entities and 3,273 foreign entities manufacturers potentially affected by the proposed rule. For purposes of the PRA estimates, FDA used a weighted average of the median hours and entities affected to calculate the respondents and burden hours. These estimates are a combination of small and large manufacturers and foreign and domestic manufactures. The estimated numbers of manufacturers in the tables below represent an estimated average portion of all domestic and foreign tobacco product manufacturers by the percentage of manufacturers that are currently not practicing one or more of the proposed requirements set forth in the proposed rule.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1120.40, 1120.142, and 1120.146 Petition for Exemption or Variance and Environmental Assessment (EA)	1	1	1	59	59

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 describes the annual reporting burden as a result of the proposed requirements in § 1120.142 for submitting petitions for exemption or variance (including EA). FDA believes this will be infrequent, so we have assigned 1 token response acknowledging the requirement.

TABLE 3—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	One-time records	Average burden per recordkeeping	Total hours	Total capital costs
One-Time Recordkeeping Burden Subpart B						
1120.12 Organization and personnel procedures and training	1,598	3	4,794	4.12	19,751	
1120.14 Tobacco product complaints	1,946	8	15,568	1.82	28,334	
1120.16 Corrective and preventive actions	1,814	8	14,512	1.82	26,412	
Total Subpart B					74,497	
One-Time Recordkeeping Burden Subpart C						
1120.32 Personnel	1,416	67	94,872	0.59	55,974	
1120.34 Buildings, facilities, and grounds	1,642	20	32,840	2.62	86,041	
1120.36 Equipment	1,186	86	101,996	1.62	165,234	
1120.38 Environment controls	2,965	8	23,720	2.42	57,402	
Total Subpart C					364,651	
One-Time Recordkeeping Burden Subpart D						
1120.42 Product development controls	2,853	12	34,236	2.90	99,284	
1120.44 Master manufacturing record	1,381	14	19,334	1.91	36,928	
Total Subpart D					136,212	
One-Time Recordkeeping Burden Subpart E						
1120.62 Purchasing controls	2,539	17	43,163	3.39	146,323	
1120.64 Acceptance activities	2,029	26	52,754	1.85	97,595	
1120.66 Process controls	1,677	35	58,695	1.84	107,999	$1,014,697
1120.68 Laboratory controls	1,293	9	11,637	1.79	20,830	10,996,249
1120.70 Production record	2,163	9	19,467	0.96	18,688	
1120.72 Representative samples	3,631	8	29,048	1.86	54,029	
1120.74 Nonconforming product	1,458	9	13,122	1.80	23,620	
1120.76 Returned product	1,594	9	14,346	1.80	25,823	
1120.78 Reprocessing and rework	1,833	8	14,664	1.86	27,275	
Total Subpart E					522,182	12,010,946
One-Time Recordkeeping Burden Subpart F						
1120.92 Packaging and labeling controls	1,683	8	13,464	3.34	44,970	
1120.94 Repackaging and Relabeling	1,523	8	12,184	3.18	38,745	
1120.98 Warning plans	1,448	8	11,584	3.18	36,837	
Total Subpart F					120,552	
One-Time Recordkeeping Burden Subpart G						
1120.102 Handling and storage	1,855	12	22,260	1.82	40,513	
1120.104 Distribution	2,028	12	24,336	1.82	44,292	
Total Subpart G					84,805	
One-Time Recordkeeping Burden Subpart H						
1120.124 Document controls	3,155	1	3,155	6.99	22,053	
Total Subpart H					22,053	
Total One-Time Burden					1,324,952	12,010,946

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL (RECURRING) RECORDKEEPING BURDEN [1]

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Annual Recordkeeping Burden Subpart B					
1120.12 Organization and personnel Procedures and training	1,598	3	4,794	2	9,588
1120.14 Tobacco product complaints	1,946	8	15,568	4	62,272
1120.16 Corrective and preventive actions	1,814	8	14,512	4	58,048
Total Subpart B					129,908

TABLE 4—ESTIMATED ANNUAL (RECURRING) RECORDKEEPING BURDEN [1]—Continued

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Annual Recordkeeping Burden Subpart C					
1120.32 Personnel	1,416	67	94,872	0.03	2,846
1120.34 Buildings, facilities, and grounds	1,642	20	32,840	0.55	18,062
1120.36 Equipment	1,186	86	101,996	0.14	14,279
1120.38 Environment controls	2,965	8	23,720	0.28	6,642
Total Subpart C					41,829
Annual Recordkeeping Burden Subpart D					
1120.42 Product development controls	2,853	12	34,236	1	34,236
1120.44 Master manufacturing record	1,381	14	19,334	0.36	6,960
Total Subpart D					41,196
Annual Recordkeeping Burden Subpart E					
1120.62 Purchasing controls	2,539	17	43,163	0.27	11,654
1120.64 Acceptance activities	2,029	26	52,754	1	52,754
1120.66 Process controls	1,677	35	58,695	1	58,695
1120.68 Laboratory controls	1,293	9	11,637	5	58,185
1120.70 Production record	2,163	9	19,467	3	58,401
1120.72 Representative samples	3,631	8	29,048	0.27	7,843
1120.74 Nonconforming product	1,458	9	13,122	4.77	62,592
1120.76 Returned product	1,594	9	14,346	4.37	62,692
1120.78 Reprocessing and rework	1,833	8	14,664	0.28	4,106
Total Subpart E					376,922
Annual Recordkeeping Burden Subpart F					
1120.92 Packaging and labeling controls	1,683	8	13,464	0.28	3,770
1120.94 Repackaging and Relabeling	1,523	8	12,184	0.27	3,290
1120.98 Warning plans	1,448	8	11,584	0.28	3,244
Total Subpart F					10,304
Annual Recordkeeping Burden Subpart G					
1120.102 Handling and storage	1,855	12	22,260	0.15	3,339
1120.104 Distribution	2,028	12	24,336	0.15	3,650
Total Subpart G					6,989
Annual Recordkeeping Burden Subpart H					
1120.124 Document controls	3,155	1	3,155	2.66	8,392
Total Subpart H					8,392
Total Annual Burden					615,540

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 represents the one-time recordkeeping requirements in the rule. FDA believes that there will be a total of 5,208 recordkeepers (the sum of 1,935 domestic and 3,273 foreign entities) who would keep records. Most of the provisions in the proposed rule require tobacco manufacturers to establish and maintain procedures. In table 3, the columns entitled ''number of recordkeepers'' and ''one-time total responses'' is totaled in the text, but not the chart. For economic purposes, the numbers in these columns are not additive because the numbers representing each section are not mutually exclusive. However, for PRA purposes these numbers are additive. We total these columns in the narrative for PRA purposes of describing and matching the data that will be submitted to OMB for approval.

Subpart B describes the proposed requirements applicable to finished and bulk tobacco product manufacturers' management systems that cover a manufacturer's organization and personnel (§ 1120.12), tobacco product complaints (§ 1120.14), and CAPA (§ 1120.16). FDA estimates that under proposed subpart B 5,358 recordkeepers will establish a total of 34,874 one-time records for a total of 74,497 one-time hours.

Subpart C of the proposed rule prescribes the proposed requirements that are specific to personnel practices (§ 1120.32), building, facilities, and grounds (§ 1120.34), equipment (§ 1120.36), and environmental controls (§ 1120.38). FDA estimates that under proposed subpart C 7,209 recordkeepers

will establish a total of 253,428 one-time records for a total of 364,651 one-time hours.

Subpart D of the proposed rule prescribes the proposed requirements for design and development activities (§ 1120.42) and MMRs (§ 1120.44). FDA estimates that under proposed subpart D 4,234 recordkeepers will establish a total of 53,570 one-time records for a total of 136,212 one-time hours.

Subpart E of the proposed rule prescribes the proposed requirements for purchasing controls (§ 1120.62), acceptance activities (§ 1120.64), production and process controls (§ 1120.66), laboratory controls (§ 1120.68), production records (§ 1120.70), sampling (§ 1120.72), nonconforming tobacco products (§ 1120.74), returned tobacco products (§ 1120.76), and reprocessing and rework (§ 1120.78). FDA estimates that under proposed subpart E 18,217 recordkeepers will establish a total of 256,896 one-time records for a total of 522,182 one-time hours.

To conduct activities related to §§ 1120.64, 1120.66, and 1120.68, some tobacco product manufacturers may purchase capital equipment such as metal detectors, pH meters, thermometers, ultrasonic flow meters, scanners, and densimeters. We estimate one-time capital costs of $1,014,697 combined under § 1120.64 acceptance activities and § 1120.66 Production and process controls, and $10,996,249 under § 1120.68 Laboratory controls for a total of $12,010,946.

Subpart F of the proposed rule prescribes the proposed requirements for packaging and labeling controls (§ 1120.92), repackaging and relabeling (§ 1120.94), and warning plans (§ 1120.98). FDA estimates that under proposed subpart F 4,654 respondents will establish a total of 37,232 one-time records for a total of 120,552 one-time hours.

Subpart G of the proposed rule prescribes the proposed requirements for activities associated with handling and storage (§ 1120.102) and distribution (§ 1120.104). FDA estimates that under proposed subpart G 3,883 respondents will establish a total of 46,596 one-time records for a total of 84,805 one-time hours.

Proposed subpart H of the proposed rule prescribes the proposed general recordkeeping and document control requirements (§ 1120.122). FDA estimates that under proposed subpart H 3,155 respondents will establish a total of 3,155 one-time records for a total of 22,053 one-time hours.

FDA estimates a total of 1,324,952 one-time hours and $12,010,946 one-time capital costs.

Table 4 estimates the annual recurring burden under the proposed rule. FDA believes that there will be a total of 5,208 recordkeepers (the sum of 1,935 domestic and 3,273 foreign entities) who would keep records. In table 4, the columns number of annual recordkeepers, and total annual responses is totaled in the text, but not in the chart. For economic purposes the numbers in these columns are not additive because the numbers representing each section are not mutually exclusive. However, for PRA purposes these numbers are additive. We total these columns in the narrative for PRA purposes of describing and matching the data that will be submitted to OMB for approval.

FDA estimates that under proposed subpart B (Management System Requirements) 5,358 recordkeepers will maintain a total of 34,874 records annually for a total of 129,908 annual hours.

FDA estimates that under proposed subpart C (Buildings, Facilities, and Equipment) 7,209 recordkeepers will maintain a total of 253,428 records annually for a total of 41,829 annual hours.

FDA estimates that under proposed subpart D (Design and Development Controls) 4,234 recordkeepers will maintain a total of 53,570 records annually for a total of 41,196 annual hours.

FDA estimates that under proposed subpart E (Process Controls) 18,217 recordkeepers will maintain a total of 256,896 records annually for a total of 376,922 annual hours.

FDA estimates that under proposed subpart F (Packaging and Labeling Controls) 4,654 recordkeepers will maintain a total of 37,232 records annually for a total of 10,304 annual hours.

FDA estimates that under proposed subpart G (Handling, Storage and Distribution) 3,883 recordkeepers will maintain a total of 46,596 records annually for a total of 6,989 annual hours.

FDA estimates that under proposed subpart H (Recordkeeping and Document Controls) 3,155 recordkeepers will maintain a total of 3,155 records annually for a total of 8,392 annual hours.

FDA estimates a total of 615,540 annual hours for this proposed rule.

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part and activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1120.96 Manufacturing code	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Proposed § 1120.96 would require that manufacturers apply a manufacturing code to the packaging and label of tobacco products. FDA lacks data on the percentage of manufacturers who apply such codes to the packaging and label of tobacco products but based on a cursory review of manufactured products it appears that many, if not all, manufacturers already apply a manufacturing code to their products. For purposes of the PRA, we have assigned one token burden hour for this activity.

Per the requirements of this proposed rule, FDA estimates the total burden will be 1,940,552 hours (59 + 1 + 1,324,952 + 615,540) and $12,010,946 one-time capital costs.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Requirements for Tobacco Product Manufacturing Practice.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves

the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

VIII. Analysis of Environmental Impact

The proposed regulation is issued pursuant to section 906(e) of the FD&C Act, which directs FDA to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, and storage of a tobacco product conform to cGMP, or HACCP methodology to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act. Under § 25.30(j), classes of actions that are categorically excluded include the issuance of cGMP and HACCP regulations. As a result, the proposed rule falls within a class of actions that are categorically excluded under § 25.30(j) and, therefore, ordinarily do not require the preparation of an EA or environmental impact statement (EIS).

An EA or EIS is required for categorically excluded actions only if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (§ 25.21). The proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. The proposed action is not anticipated to pose the potential for serious harm to the environment or to adversely affect a species or the critical habitat of a species described in § 25.21(b). Thus, FDA has determined that no extraordinary circumstances exist that would require preparation of an EA or an EIS.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. Section 4(a) of the E.O. requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that ''no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . good manufacturing standards.''

This rule is being issued under section 906(e) of the FD&C Act, which directs FDA to prescribe regulations relating to good manufacturing practice. Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

X. Consultation and Coordination With Indian Tribal Governments

FDA has analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively concluded that the rule does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The Agency solicits comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XI. References

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

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List of Subjects in 21 CFR Part 1120

Smoking, Tobacco, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act [LEGAL CITATION] and under authority delegated to the Commissioner of Food and Drugs, amend chapter I of title 21 of the Code of Federal Regulations by adding part 1120 to subchapter K to read as follows:

PART 1120—REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

Sec.

Subpart A—General Provisions

1120.1 Scope.
1120.3 Definitions.

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Subpart F—Packaging and Labeling Controls

1120.92 Packaging and labeling controls.
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Subpart G—Handling, Storage, and Distribution

1120.102 Handling and storage.
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Subpart I—Small Tobacco Product Manufacturers

1120.130 Compliance date for small tobacco product manufacturers.

Subpart J—Exemptions and Variances

1120.140 Exemptions and variances.
1120.142 Petition for an exemption or variance.
1120.144 Referral to the Tobacco Products Scientific Advisory Committee.
1120.146 Petition determination.
1120.148 Hearing.

Authority: 21 U.S.C. 371, 21 U.S.C. 374, 21 U.S.C. 381, 21 U.S.C. 387b, 21 U.S.C. 387c, 21 U.S.C. 387e(g), 21 U.S.C. 387f(e), and 21 U.S.C. 387i.

Subpart A—General Provisions

§ 1120.1 Scope.

(a) This part sets forth the current tobacco product manufacturing practice (TPMP) requirements under the Federal Food, Drug, and Cosmetic Act. The requirements of this part apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act, except finished and bulk accessories of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco. Manufacturers of finished and bulk tobacco products include specification developers, contract manufacturers, and repackagers/relabelers. The requirements in this part govern the methods used in, and the facilities and controls used for, the preproduction design validation, manufacture, packing, and storage of finished and bulk tobacco products by finished and bulk tobacco product manufacturers.

(b) If a tobacco product manufacturer engages in some operations subject to the requirements of this part, and not others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

(c) The term ''where appropriate'' is used several times in this part. When a requirement is qualified with ''where appropriate,'' it is deemed to be appropriate unless the tobacco product manufacturer documents in writing an adequate justification prior to abstaining from implementing the requirement. An adequate justification would address why abstaining from the requirement would not result in a nonconforming tobacco product, or in the manufacturer not being able to carry out necessary corrective actions.

(d) The requirements in this part are intended to protect the public health and assure that tobacco products are in compliance with the relevant provisions of the Federal Food, Drug, and Cosmetic Act. The failure to comply with any applicable provision in this part renders a product adulterated under section 902(7) of the Federal Food, Drug, and Cosmetic Act.

§ 1120.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

Batch means a specific identified amount of a tobacco product produced in a unit of time or quantity and that is intended to have the same specifications.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Bulk tobacco product means a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product.

Characteristic means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Contaminated tobacco product means a tobacco product that contains a substance not ordinarily contained in that tobacco product. An example of a contaminated tobacco product is a smokeless tobacco product with metal fragments in the tobacco filler.

Design means the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product.

Direct accounts means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

Establish and maintain means to define, document in writing, implement, follow, and update.

Equipment means any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product.

Finished tobacco product means a tobacco product, including any component or part, sealed in final packaging. Examples of finished tobacco products include a pack of cigarettes, a

can of moist snuff, and rolling papers, filters, filter tubes, or e-liquids sold to consumers.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through chemical action during tobacco product manufacturing.

Label means a display of written, printed, or graphic matter upon the immediate container of any article.

Labeling means all labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers; or

(2) Accompanying such article.

Management with executive responsibility means one or more designated personnel who have the authority and responsibility to ensure compliance with TPMP requirements, including allocating resources or making changes to the organizational structure, buildings, facilities, equipment, or the manufacture, preproduction design validation, packing, and storage of a tobacco product.

Manual method, process, or procedure means any nonautomated method, process, or procedure, including processes performed by hand with or without the use of equipment.

Manufacturing means the manufacturing, fabricating, assembling, processing, or labeling, including the repackaging or relabeling, of a tobacco product. Manufacturing includes establishing the specifications of a finished or bulk tobacco product.

Manufacturing code means any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date followed by the batch number.

Manufacturing date means the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished or bulk tobacco product is packaged for distribution.

Manufacturing material means material used in or used to facilitate the manufacturing process that is not equipment and is not intended to be part of the product.

Master manufacturing record (MMR) means a document or designated compilation of documents containing the established specifications for a tobacco product, including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product.

Nonconforming tobacco product means any tobacco product that does not meet a product specification in the MMR (see § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see § 1120.44(a)(3)); or is a contaminated tobacco product.

Not normally associated means not an inherent risk of using the tobacco product. For example, bodily injury caused by an exploding electronic nicotine delivery system (ENDS) battery would be considered not normally associated with the use of ENDS products.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers (this is also referred to as final package or final packaging), or in which a bulk tobacco product is offered for sale, sold, or otherwise distributed (including commercial distribution and interplant transfers).

Personnel means all persons, including managers, staff, consultants, contractors, and third-party entities, performing services for the manufacturer subject to this part. This definition includes independent contractors performing services for the manufacturer.

Relabeling means operations in which the labeling of a finished tobacco product is subsequently changed or replaced.

Repackaging means operations in which the packaging of a finished tobacco product is subsequently changed or replaced.

Representative sample means a sample that consists of a number of units that are drawn based on a valid scientific rationale (such as random sampling) and intended to ensure that the sample accurately reflects the material being sampled.

Reprocessing means using a tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product.

Returned tobacco product means a commercially distributed finished or bulk tobacco product returned to the tobacco manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or a member of the public.

Rework means action taken on a nonconforming or returned tobacco product to ensure the product meets the specifications and other requirements of the MMR of a subsequently manufactured tobacco product before it is released for further manufacturing or distribution.

Small tobacco product manufacturer means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

Specification means any requirement with which a product, process, service, or other activity must conform.

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term ''tobacco product'' does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Tobacco product-contact surface means a surface that comes into contact with a tobacco product and a surface from which drainage (or other transfer) ordinarily occurs onto the tobacco product or onto surfaces that come into contact with the tobacco product during the normal course of operations. For example, tobacco product-contact surfaces include surfaces of equipment that come into contact with the tobacco product.

Tobacco product manufacturer means any person(s), including a repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States. Tobacco product manufacturer includes any person(s) establishing specifications for a tobacco product.

Unique identifier means information, such as a code or number, that is maintained for each accepted incoming tobacco product that would enable the tobacco product manufacturer and FDA to identify the supplier and unique shipment of the incoming product.

Validation means confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled.

Verification means confirmation by examination and objective evidence that specified requirements have been fulfilled.

Subpart B—Management System Requirements

§ 1120.12 Organization and personnel.

(a) *Organization.* Each finished and bulk tobacco product manufacturer must establish and maintain an organizational structure to ensure that manufacturing operations meet the requirements of this part.

(b) *Personnel qualifications.* Each finished and bulk tobacco product manufacturer must have sufficient personnel to carry out the requirements of this part. Personnel must have the background, education, training, and experience, or any combination thereof, needed to carry out the requirements under this part. Each manufacturer must maintain appropriate written records of the background, education, training, and experience of its personnel.

(c) *Responsibility.* Each finished and bulk tobacco product manufacturer must designate, in writing, appropriate responsibility and authority for all personnel who perform an activity subject to this part.

(d) *Management with executive responsibility.* Each finished and bulk tobacco product manufacturer must designate, in writing, management with executive responsibility that has the duty, power, and responsibility to implement the requirements under this part. Management with executive responsibility must establish and maintain required processes and procedures to ensure compliance with the requirements under this part. Management with executive responsibility must ensure the requirements of this part are communicated, understood, implemented, and followed at all levels of the organization.

(e) *Training.* Each finished and bulk tobacco product manufacturer must establish and maintain training procedures for identifying training needs and establishing training frequency for personnel based on the work the employee performs. The manufacturer must train personnel on their assigned responsibility and on the tobacco product manufacturing practice requirements relevant to their responsibility.

(f) *Records.* The training records required under § 1120.12(b) must include:

(1) The type and description of the training;

(2) The training date;

(3) The names of parties performing and taking the training; and

(4) Documentation supporting completion.

§ 1120.14 Tobacco product complaints.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all complaints. The procedure must ensure that all complaints are:

(1) Processed upon receipt in a uniform and timely manner;

(2) Evaluated and, if necessary, investigated with any followup action taken, according to paragraphs (b) and (c) of this section; and

(3) Documented according to paragraph (e) of this section.

(b) *Evaluation.* All complaints must be evaluated to determine whether the complaint could be related to:

(1) A nonconforming tobacco product;

(2) A product design issue; or

(3) Any adverse experience that is required to be reported under a regulation promulgated under section 909(a) of the Federal Food, Drug, and Cosmetic Act.

(c) *Investigation.* (1) If the evaluation determines that the complaint could be related to paragraphs (b)(1) through (3) of this section, an investigation must be performed except as provided in paragraph (d) of this section.

(2) The investigation must include:

(i) The scope and cause of the issue;

(ii) The risk of illness or injury posed by the issue;

(iii) Whether any other followup action is necessary, including whether a corrective and preventative action is necessary under § 1120.16.

(d) *Exception.* An investigation required under paragraph (c) of this section must be completed unless an investigation has already been performed for a similar complaint and the tobacco product manufacturer determines and documents that the previous investigation results apply and another investigation is not necessary.

(e) *Complaint records.* Each finished and bulk tobacco product manufacturer must maintain complaint records. The record documenting the complaint, including all evaluation, investigation, and any followup action, must be maintained according to the procedures identified under paragraph (a) of this section. Complaints received that could be related to a nonconforming tobacco product, design issues, or any adverse experience that is required to be reported under a regulation promulgated under section 909(a) of the Federal Food, Drug, and Cosmetic Act, and that may result in a risk of illness, injury, or death not normally associated with the use of tobacco products must be clearly identified or separated. Complaint records must include the following information, if available:

(1) Name of the product, including brand and sub-brand;

(2) Description of the product;

(3) Manufacturing code;

(4) Date complaint received;

(5) Format of complaint (*i.e.,* oral or written);

(6) Name, address, and phone number of complainant;

(7) Nature and details of complaint, including how the product was used;

(8) Identification of individual(s) receiving complaint;

(9) Record of evaluation by the manufacturer including the name of the individual(s) performing the evaluation;

(10) If no investigation is undertaken, the name of the individual(s) responsible for that decision and the rationale for the decision;

(11) Investigation date(s);

(12) Record of investigational activities performed and who performed the activity;

(13) Results of investigation; and

(14) Followup action taken, including any reply to the complainant or any corrective and preventive action.

(f) *Unavailable complaint records.* If information identified under paragraph (e) of this section is unavailable, the record must include:

(1) Documentation of the attempt(s) to obtain the information; and

(2) Why the information is not included.

§ 1120.16 Corrective and preventive actions.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for implementing corrective and preventive actions. The procedures must include requirements for:

(1) Reviewing and analyzing processes, process control records, complaints, production records, returned products, reprocessed products, reworked products, and other sources of data to identify existing and potential causes of nonconforming tobacco product and design problems. Appropriate statistical methodology must be employed where necessary to detect recurring problems;

(2) Investigating the cause of design problems or nonconformities relating to the product or manufacturing process;

(3) Identifying and taking the action needed to correct and prevent the recurrence of design problems and nonconformities and other related problems;

(4) Verifying or validating the corrective and preventive action to ensure that the action taken is effective and does not adversely affect the tobacco product;

(5) Implementing and documenting changes to tobacco product specifications, manufacturing methods and production process procedures, and packaging, labeling, and labels needed to correct and prevent identified causes of the design problem or nonconformity; and

(6) Disseminating information related to the design problem or nonconforming product and the corrective and preventive action taken to:

(i) Management with executive responsibility;

(ii) Those responsible for acceptance activities of a tobacco product; and

(iii) Personnel responsible for identifying training needs in accordance with § 1120.12(e).

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities conducted under this section. Records must include the date and time, individual performing the activity, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Subpart C—Buildings, Facilities, and Equipment

§ 1120.32 Personnel practices.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the cleanliness, personal practices, and apparel of personnel. Such procedures must include requirements to ensure that contact between the personnel and the tobacco product or the environment would not result in contamination of the tobacco product.

§ 1120.34 Buildings, facilities, and grounds.

(a) *Buildings and facilities.* Each finished and bulk tobacco product manufacturer must ensure that any buildings and facilities used in or for the manufacture, packaging, or storage of a tobacco product are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. Each building and facility must be maintained in an appropriate condition to prevent contamination. Buildings and facilities must have adequate:

(1) Lighting;

(2) Heating, ventilation, and cooling;

(3) Plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination or creating insanitary conditions;

(4) Waste collection, storage, and disposal (including not creating malodors that contaminate tobacco products or result in an attraction, harborage, or breeding place for animals and pests); and

(5) Readily accessible handwashing and toilet facilities. The facilities must provide for water at suitable temperatures and appropriate cleaning and sanitation materials.

(b) *Grounds.* Each finished and bulk tobacco product manufacturer must maintain facility grounds in a condition to prevent contamination.

(c) *Water.* Each finished and bulk tobacco product manufacturer must ensure water used in the manufacturing process, including water that is or may become part of the tobacco product (*e.g.,* water used as an ingredient or water used on tobacco product-contact surface) is potable, will not contaminate the tobacco product, is maintained under positive pressure, and is supplied from sources that comply with all applicable Federal, State, and local requirements.

(d) *Cleaning and sanitation.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the cleaning and sanitation of buildings, facilities, and grounds, including procedures for the use of any cleaning compounds, sanitizing agents, pesticide chemicals, rodenticides, insecticides, fungicides, fumigating agents, and other toxic materials.

(1) These procedures must detail the cleaning schedules, equipment, and materials to be used in the cleaning and sanitizing, as appropriate, of the buildings, facilities, and grounds.

(2) The procedures must include measures to ensure that materials used for cleaning and sanitation are identified, held, used, and stored in a manner to protect against contamination of tobacco products and tobacco product-contact surfaces.

(3) The use of cleaning and sanitation materials must also comply with all applicable Federal, State, and local requirements related to their application, use, or storage.

(e) *Animal and pest control.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds to protect against contamination of tobacco products. These procedures must include requirements for establishing threshold criteria for animals and pests. The procedures also must include requirements that any pesticide used in the buildings, facilities, and grounds be registered in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135) and used in accordance with its label, as applicable, and used in a manner that protects against contamination of the tobacco product.

(f) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of cleaning and sanitation, and animal and pest control activities required under this section. These records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.36 Equipment.

(a) *Design and construction.* Each finished and bulk tobacco product manufacturer must ensure that all equipment is appropriately designed and constructed and is suitable for its intended purpose.

(b) *Maintenance.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures, including the methods and schedules, for the routine cleaning and maintenance of equipment, to ensure proper performance of equipment and prevent contamination. The procedures must provide for any change over of tobacco product and account for changes, limitations, or adjustment to the equipment.

(c) *Identification.* Each finished and bulk tobacco product manufacturer must identify (electronically, by signage, or other method of identification), if applicable, all processing lines and major equipment to be used during manufacturing to prevent mixups and contamination.

(d) *Testing, monitoring, and measuring equipment.* (1) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for all testing, monitoring, and measuring equipment to ensure the equipment is capable of producing accurate and reliable results.

(2) All testing, monitoring, and measuring equipment must be identified and disabled, removed, replaced, or

repaired when it is no longer suitable for its intended purpose or when it is no longer capable of producing accurate and reliable results.

(3) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the routine calibration of testing, monitoring, and measuring equipment. These procedures must describe an appropriate reference standard and include specific directions and acceptance criteria for the limits of accuracy and precision. Equipment must be calibrated:

(i) Before its first use;

(ii) Thereafter, at a frequency determined by the equipment manufacturer or at intervals necessary to ensure accurate and reliable results; and

(iii) After repair or maintenance.

(e) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. These records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.38 Environmental controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to adequately control environmental conditions, where appropriate. Environmental control systems must be maintained and monitored to verify that the environmental controls, including necessary equipment, are adequate and functioning properly.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section, including maintenance and monitoring. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Subpart D—Design and Development Controls

§ 1120.42 Design and development activities.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. These procedures must include the following requirements:

(1) *Risk management process.* These procedures must use a risk management process that includes the following:

(i) *Risk assessment.* Each finished and bulk tobacco product manufacturer must perform a risk assessment that includes risk identification, risk analysis, and risk evaluation. Risk identification is identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage. Risk identification must include risks that may occur with normal use and with reasonably foreseeable misuse of a tobacco product. Risk analysis is an analysis of the nature and level of risk for each identified known or reasonably foreseeable risk that takes into account the likelihood of occurrence of the risk and the consequences of occurrence of the risk (*i.e.,* severity of the potential harm). Risk evaluation is a determination of the significance of the risk and what type of risk treatment is needed.

(ii) *Risk treatment.* Each finished and bulk tobacco product manufacturer must treat all identified risks, including risks addressed in applicable tobacco product standards. Risk treatment must significantly minimize or prevent risks:

(A) That are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or

(B) That the manufacturer determines constitute an unacceptable level of risk. Risks addressed in any applicable tobacco product standards must be treated in a manner that ensures the tobacco product will conform to the specifications and requirements established in the tobacco product standard.

(iii) *Reassessment.* Each finished and bulk tobacco product manufacturer must reassess the risks whenever the manufacturer becomes aware of new information that could change the risk assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures, in accordance with paragraphs (a)(1)(i) and (ii) of this section.

(2) *Design verification and validation.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must perform design verification to confirm that the tobacco product and its package meet specifications and design validation to assess the performance of the tobacco product;

(3) *Design approval.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must ensure the product and package design is approved by a designated, authorized individual;

(4) *Design transfer.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must transfer the approved product and package specifications to the master manufacturing record; and

(5) *Design changes.* Each finished and bulk tobacco product manufacturer must, where appropriate, utilize the processes under paragraphs (a)(2) to (4) of this section for design changes before the changes are implemented.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.44 Master manufacturing record.

(a) Each tobacco product manufacturer must establish and maintain a master manufacturing record (MMR) for each finished and bulk tobacco product they manufacture for distribution. The MMR must include the following information:

(1) Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications. The tobacco product specifications must include:

(i) The identity and amount of any components or parts, ingredients, additives, and materials in the finished or bulk tobacco product;

(ii) The finished or bulk tobacco product design, an identification of the product's heating source (if any), a discussion of intended user operation, and any relevant product drawings or schematics;

(iii) Any specification necessary to ensure that the tobacco product meets any applicable product standard established under section 907 of the Federal Food, Drug, and Cosmetic Act; and

(iv) Specification(s) for pesticide chemical residue(s) for raw tobacco.

(2) All relevant manufacturing methods and production process procedures. The manufacturing methods

and production process procedures must include any process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities (inspections, testing, evaluation, and other verification activities); and

(3) All packaging, labeling, and labels approved by the tobacco product manufacturer for use with the finished or bulk tobacco product.

(b) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the review and approval of the MMR, including any changes made to the MMR after initial approval. Under these procedures, a designated, qualified individual must review and approve all MMR information before it is implemented in the manufacture of finished and bulk tobacco products for distribution. The designated, qualified individual's approval of the MMR must be documented by date, name, and signature of the individual(s) approving the document. The procedures for MMR review and approval must ensure that the designated, qualified individual confirms that any design activities conducted to support the tobacco product specifications have been completed in accordance with the product design and development procedures established by the manufacturer under § 1120.42 and that the resulting production specifications are correctly transferred into the MMR.

(c) The MMR must describe which methods and procedures established under paragraph (a)(2) of this section and related sections, including §§ 1120.62 (Purchasing controls), 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls), are used to ensure that the tobacco product is in conformance with each tobacco product specification established under paragraph (a)(1) of this section.

Subpart E—Process Controls

§ 1120.62 Purchasing controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that each purchased or otherwise received product or service related to the manufacture of a finished or bulk tobacco product is from a qualified supplier and conforms to established specifications.

(b) *Qualification.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for qualifying its suppliers. These procedures must include the following requirements for qualification of suppliers:

(1) Evaluating and selecting potential suppliers based on their ability to meet written requirements set by the manufacturer (*e.g.,* past history, onsite audits, test results);

(2) Defining the type and extent of control to be exercised over selected suppliers and their product or service, based on evaluation results;

(3) Developing a list of qualified suppliers and the product(s) or service(s) they provide, and updating this information periodically; and

(4) Monitoring qualified suppliers to ensure they meet specified requirements and performing reevaluations as needed.

(c) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities conducted under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. These records also must include a written agreement that the supplier will notify the manufacturer of any change in the product or service so that the manufacturer can determine whether the change may affect the specifications of the finished or bulk tobacco product established in accordance with § 1120.44(a)(1).

§ 1120.64 Acceptance activities.

(a) *General.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for acceptance activities, including acceptance criteria, in accordance with paragraphs (b) through (d) of this section.

(b)(1) *Incoming acceptance activities.* The acceptance activities procedures must address the acceptance activities for all incoming products to ensure that any specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met and that such products are not contaminated or deteriorated. The incoming acceptance procedures must ensure that each accepted incoming tobacco product is designated by a unique identifier, which must be maintained throughout manufacturing and documented in accordance with § 1120.70(b)(5). For incoming finished or bulk tobacco product, the unique identifier must include or be traceable to the manufacturing code on the packaging or label of the finished or bulk tobacco product. The results of incoming acceptance activities must be reviewed and approved to ensure the incoming tobacco product specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met, and that such products are not contaminated or deteriorated.

(2) *Pesticide chemical residue.* The acceptance activities procedures must address the testing and acceptance of raw tobacco to ensure that it meets established specifications for pesticide chemical residue set by the manufacturer and complies with any applicable tolerance under Federal law.

(3) *Contamination.* All incoming tobacco products must be evaluated for contamination or deterioration.

(c) *In-process and final acceptance activities.* The acceptance activities procedures must address in-process and/or final acceptance activities to ensure that each finished or bulk tobacco product meets the specifications established under § 1120.44. The results of these acceptance activities must be reviewed and approved to ensure the finished and bulk tobacco product specifications established under § 1120.44 are met.

(d) *Acceptance status.* Each finished and bulk tobacco product manufacturer must identify by suitable means the acceptance status of a tobacco product, indicating whether the tobacco product is a conforming or nonconforming tobacco product. The identification of the acceptance status must be maintained from receipt of incoming products throughout manufacturing and until the finished or bulk tobacco product passes required acceptance activities and is released for distribution.

(e) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, acceptance criteria, any information that demonstrates the requirement was met, equipment used if applicable, and any data or calculations necessary to reconstruct the results.

§ 1120.66 Production processes and controls.

(a) *General.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for production processes, including process controls, to ensure that tobacco products conform to the requirements established in the MMR in accordance with § 1120.44. Production process procedures must address the following:

(1) Production process specifications with relevant acceptance criteria.

(2) Relevant process controls, such as any monitoring and acceptance activities (inspection, testing, evaluation, and other verification activities).

(3) Any deviations from the production process specifications and established acceptance criteria, or from relevant process controls, must be investigated to determine if they result in a nonconforming tobacco product. The disposition of any product affected by a deviation must be documented.

(4) All changes to production processes, including process controls, must be evaluated to determine their impact on the tobacco product specifications in the MMR. If any production process changes result in a change to the tobacco product specifications, the manufacturer must ensure that procedures applicable to changes in tobacco product specifications are followed in accordance with §§ 1120.42 and 1120.44 and update the tobacco product specifications in the MMR as needed. Changes to validated processes must be revalidated before implementation, where appropriate.

(b) *Process validation.* In addition to the requirements in paragraph (a) of this section, the production process procedures must include the following requirements for process validation, if applicable. If the results of a process, including automated processes, cannot be fully verified, a manufacturer must validate the process to demonstrate that it will produce a tobacco product that conforms to the specifications established under § 1120.44(a)(1). Process validation must use appropriate objective measures and valid scientific tools and analyses to maintain the process in a state of control. The process validation must include the following:

(1) *Process design.* Each finished and bulk tobacco product manufacturer must design a production process for the manufacture of its tobacco products. The process design must address the capability and functionality of the production process and establish a strategy for process control.

(2) *Process qualification.* Each finished and bulk tobacco product manufacturer must perform:

(i) Process qualification to determine if the process is capable of reproducible manufacturing; and

(ii) Process performance qualification to confirm the process design and demonstrate that the manufacturing process performs as expected in accordance with established criteria, which must be documented in a written protocol.

(3) *Continued process verification.* Each finished and bulk tobacco product manufacturer must monitor the production process using data collected from records required under this part and valid scientific tools to detect variability and ensure that the process remains in a state of control.

(c) *Additional requirements.* In addition to the requirements in paragraph (a) of this section, the production process procedures must include the following requirements, if applicable:

(1) *Manual methods.* If a production process includes a manual method or process, the production process procedures must describe the manual method or process in sufficient detail to ensure that the tobacco product meets established specifications and include if applicable, the criteria for workmanship using a standard or approved model sample.

(2) *Manufacturing material.* The production process procedures must address the use and removal of manufacturing material if such material could reasonably be expected to contaminate the tobacco product or otherwise result in a nonconforming tobacco product.

(d) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.68 Laboratory controls.

(a) *Competency.* When using a laboratory to conduct activities under this part, each finished and bulk tobacco product manufacturer must demonstrate, through appropriate documentation, the laboratory's competence to perform laboratory activities associated with the manufacture of finished and bulk tobacco products.

(b) *Controls.* Each finished and bulk tobacco product manufacturer must establish and maintain laboratory control procedures for any laboratory activities that are conducted under this part. Laboratory control procedures must include the following requirements:

(1) Use of scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose;

(2) Use of representative samples in accordance with § 1120.72; and

(3) Demonstration of analytical control.

(c) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.70 Production record.

(a) *Production record.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that a production record is prepared for each batch of finished or bulk tobacco product to demonstrate conformity with the requirements established in the MMR in accordance with § 1120.44. Designated personnel must review and approve the production record for release of each batch of finished or bulk tobacco product into distribution.

(b) *Production record content.* The production record must include, or refer to the location of:

(1) The manufacturing code;

(2) The quantity of finished or bulk tobacco product manufactured in the batch;

(3) Identification of major equipment and processing lines used in manufacturing the batch of finished or bulk tobacco product;

(4) Records of any activities performed under this part necessary to demonstrate that the batch of finished or bulk tobacco product was manufactured to conform with requirements established in the MMR under § 1120.44;

(5) All unique identifiers of all accepted incoming tobacco products, including components or parts, ingredients, additives, and materials, used in the manufacture of the batch of finished or bulk tobacco product;

(6) If any finished or bulk tobacco product was used in the manufacturing of the batch, the manufacturing code for that finished or bulk tobacco product;

(7) Actual or copies of the packaging, labeling, and labels used with the finished or bulk tobacco product; and

(8) The name(s) and signature(s) of the designated individual(s) reviewing and approving the production record for release of the batch of finished or bulk tobacco product into distribution.

§ 1120.72 Sampling.

For any sampling performed under this part, each tobacco product manufacturer must establish and maintain an adequate sampling plan

using representative samples. The sampling plan must include:

(a) The intended purpose of the sampling;

(b) The scientific technique or method used to establish the sample size, including an explanation of how the sample size is representative of the material being sampled; and

(c) The method of sampling.

§ 1120.74 Nonconforming tobacco product.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the control and disposition of nonconforming tobacco product. The procedures must include the following requirements:

(a) *Identification and segregation.* Each finished and bulk tobacco product manufacturer must identify and segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition.

(b) *Investigation.* Each finished and bulk tobacco product manufacturer must investigate all potential nonconforming tobacco products.

(1) To determine if the product is nonconforming, the investigation must include an examination of relevant production processes and controls, laboratory testing, complaints, and any other relevant records and sources of information.

(2) For products determined to be nonconforming, the investigation must also determine:

(i) The scope and cause of the nonconformance; and

(ii) The risk of illness or injury posed by the nonconformance.

(c) *Disposition and followup.* Each finished and bulk tobacco product manufacturer must determine the disposition of all nonconforming tobacco products and conduct any necessary followup. If the disposition decision is that the tobacco product can be released for distribution without rework, an adequate written justification must be provided. An adequate written justification must address why releasing the nonconforming product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded. Nonconforming product cannot be released for distribution without rework or an adequate justification.

(d) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time of the activity, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.76 Returned tobacco product.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the control and disposition of returned tobacco product. The procedures must include the following requirements:

(1) *Identification.* Each finished and bulk tobacco product manufacturer must identify returned tobacco product with the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, and reason for the return.

(2) *Segregation.* Each finished and bulk tobacco product manufacturer must segregate identified returned tobacco product in a manner that prevents mixups and use of returned product prior to evaluation and disposition.

(3) *Evaluation and disposition.* Each finished and bulk tobacco product manufacturer must evaluate identified returned tobacco product and determine its disposition. The returned tobacco product must be discarded unless the manufacturer determines that it can be reworked under § 1120.78 or released for distribution based on an adequate written justification.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. Records of evaluation and disposition must include the product name, manufacturing code, quantity returned, date the manufacturer received the returned product and reason for the return, disposition decision and any justification, and the name of the individual making the decision.

§ 1120.78 Reprocessing and rework.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for reprocessing and reworking tobacco products. The procedures must include:

(1) Evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual. Tobacco product is appropriate for reprocessing if it is uncontaminated and has the same specifications as those in the MMR of the subsequently manufactured tobacco product. Tobacco product is appropriate for rework if further manufacturing can correct the nonconformity and the product can meet specifications and other requirements in the MMR of the subsequently manufactured tobacco product.

(2) Production processes, including process controls, in accordance with § 1120.66(a), and acceptance activities, in accordance with § 1120.64(c), used to ensure the reprocessed or reworked tobacco product conforms to the requirements established under § 1120.44 for the subsequently manufactured tobacco product.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. The production record of any finished or bulk tobacco product that includes reprocessed or reworked product must include the amount, any unique identifier(s) assigned under § 1120.64(b), any batch number, and any manufacturing code associated with the reprocessed or reworked product.

Subpart F—Packaging and Labeling Controls

§ 1120.92 Packaging and labeling controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control packaging and labeling activities to prevent mixups and to ensure that all packaging and labeling are approved for use by the manufacturer and comply with all requirements of the MMR as well as all other applicable requirements of the Federal Food, Drug, and Cosmetic Act, the Comprehensive Smokeless Tobacco Health Education Act, and the Federal Cigarette Labeling and Advertising Act and their implementing regulations. The procedures must address the following:

(1) *Label integrity.* Labels must be indelibly printed on or permanently affixed to finished and bulk tobacco product packages, so they remain legible, prominent, and conspicuous during the customary conditions of processing, packing, storage, handling, distribution, and use.

(2) *Design and construction.* Each finished and bulk tobacco product manufacturer must ensure that:

(i) Packaging and labeling used do not contaminate or otherwise render the tobacco product adulterated or misbranded; and

(ii) Storage and shipping cases or containers of finished or bulk tobacco products are designed and constructed to protect against contamination and adulteration of the products during the customary conditions of storage, handling, and distribution.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.94 Repackaging and relabeling.

(a) *Procedures.* Each finished tobacco product manufacturer must establish and maintain procedures to control repackaging and relabeling activities. The procedures must address all requirements described in § 1120.92.

(b) *Records.* Each finished tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.96 Manufacturing code.

(a) Each finished and bulk tobacco product manufacturer must apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. For a finished tobacco product, the manufacturing code must be applied in a manner that assures it will remain on the packaging or label through the expected duration of use of the tobacco product by the consumer. For a bulk tobacco product, the manufacturing code must be applied in a manner that assures it will remain on the packaging or label until the product is received by the finished tobacco product manufacturer, including a packager or labeler.

(b) The manufacturing code for each finished and bulk tobacco product must be permanently affixed, legible, conspicuous, and prominent.

(c) The manufacturing code must contain the following information listed in the following order:

(1) The manufacturing date in 2-digit numerical values in the month-day-year format (MMDDYY); and

(2) The finished or bulk tobacco product batch number.

§ 1120.98 Warning plans.

(a) Each finished tobacco product manufacturer required to comply with a warning plan for tobacco product packaging must establish and maintain procedures to implement the requirements of such warning plan. Such procedures must include requirements for inspection of packaging before distribution to ensure that the finished tobacco product labels bear the required warning statements in accordance with the warning plan.

(b) Each finished tobacco product manufacturer required to comply with a warning plan for tobacco product packaging must maintain records that demonstrate that the manufacturer is in compliance with the warning plan.

Subpart G—Handling, Storage, and Distribution

§ 1120.102 Handling and storage.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products.

§ 1120.104 Distribution.

(a) *Distribution procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure the following:

(1) Finished and bulk tobacco products are distributed to the initial consignee under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products; and

(2) Only those finished and bulk tobacco products approved for release are distributed.

(b) *Distribution records.* Each finished and bulk tobacco product manufacturer must maintain distribution records that include:

(1) The name and address of the initial consignee;

(2) The identification and quantity of finished or bulk tobacco products shipped;

(3) The date shipped; and

(4) The manufacturing code(s).

(c) *Records of direct accounts.* Each finished and bulk tobacco product manufacturer must maintain a list of direct accounts (including wholesalers, distributors, and retailers), including their name, address, and contact information.

Subpart H—Recordkeeping and Document Controls

§ 1120.122 Recordkeeping and document control requirements.

(a) All documents and records required by this part must comply with the following requirements:

(1) All documents and records must be written in English, or an accurate English translation must be made available upon request.

(2) All documents and records that are associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records that are not associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date they were last in effect.

(3) All documents and records must be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. These documents and records, including those not stored at the establishment, must be made readily accessible to FDA during the retention period for inspection and photocopying or other means of reproduction. Original or true copies of documents and records that can be immediately retrieved from another location, including by computer or other electronic means, meet the requirements of this paragraph.

(b)(1) All records required by this part, regardless of storage medium, must be attributable, legible, contemporaneously recorded, original, and accurate.

(2) For the purposes of this subpart, these terms are defined as the following:

(i) *Attributable.* Attributable means that the data in a record is traceable to its source. This means it should be attributable to the originator of the data, whether that source is an individual, an automated piece of equipment, or individual operating equipment.

(ii) *Legible.* Legible means the record is permanently recorded in a readable format. A legible record prevents loss and preserves traceability of changes without obscuring the original entry or subsequent additions or deletions.

(iii) *Contemporaneously recorded.* Contemporaneously recorded means

that data is recorded at the time the procedure, assessment, observation, or other activity is performed.

(iv) *Original.* Original means the record reflects the first capture of the data and all information related to all subsequent changes required to fully reconstruct the TPMP activities. An original record preserves the record content and the meaning of the data, including associated metadata. Original records may be static or dynamic. A static record, such as a paper record, is fixed and allows little or no interaction between the user and record content. Records in a dynamic state allow the user to interact with the information.

(v) *Accurate.* Accurate means that the data in a record is correct, truthful, complete, valid, and reliable. All records required under this part, including the associated data and metadata, must be accurate.

(c) Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control all documents established to meet the requirements of this part. The procedures must provide for the following:

(1) *Document approval and distribution.* Each finished and bulk tobacco product manufacturer must review and approve all documents established to meet the requirements of this part before implementation. The approval must include the date, name, and signature of the individual(s) approving the document. Documents established to meet the requirements of this part must be available at all locations for which they are designated, used, or otherwise necessary, and all such documents that are superseded and obsolete documents must be promptly removed from all points of use or otherwise prevented from unintended use.

(2) *Document changes.* Before implementation, changes to documents established to meet the requirements of this part must be reviewed and approved by an individual(s) in the same function or part of the organization that performed the original review and approval. Approved changes must be communicated to the appropriate personnel in a timely manner. Superseded and obsolete documents established to meet the requirements of this part must be archived. Each tobacco product manufacturer must maintain records of changes to documents established to meet the requirements of this part. Change records must include:

(i) A description of the change;

(ii) Identification of the affected documents;

(iii) The name and signature of the approving individual(s);

(iv) The approval date; and

(v) The date the change becomes effective.

Subpart I—Small Tobacco Product Manufacturers

§ 1120.130 Compliance date for small tobacco product manufacturers.

Small tobacco product manufacturers of finished and bulk tobacco products shall not be required to comply with the requirements in this part until [DATE 4 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

Subpart J—Exemptions and Variances

§ 1120.140 Exemptions and variances.

Under section 906(e)(2) of the Federal Food, Drug, and Cosmetic Act, any person subject to any requirement prescribed in this part may petition FDA for a permanent or temporary exemption or variance from such requirement. The petitioner remains subject to the relevant requirement unless FDA grants the petition for an exemption or variance under § 1120.146. To petition for an exemption or variance, the petitioner must submit all information supporting the petition in an electronic format that FDA can process, review, and archive. If the petitioner is unable to submit a petition in an electronic format, the petitioner may submit a written request to FDA requesting FDA allowance of an alternative format and explaining in detail why the petitioner cannot submit the petition in an electronic format. Such request must include an explanation of why an alternative format is necessary. All petitions for exemptions or variances, including all supporting information, and all requests to submit petitions in an alternate format must be legible and in the English language.

§ 1120.142 Petition for an exemption or variance.

A petition for an exemption or variance from a requirement in this part must contain:

(a) The petitioner's name, address, and contact information;

(b) Identification of the tobacco product(s);

(c) The requirement(s) in this part for which an exemption or variance is requested;

(d) A detailed explanation of why the exemption or variance is requested, including why the tobacco product manufacturer is not able to comply with the requirement(s) of this part;

(e) The duration of the proposed exemption or variance;

(f) For a petition for a variance, a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement(s) in this part, as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health is protected, the tobacco product(s) will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act;

(g) For a petition for an exemption, a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement(s) is not required to assure that: the public health is protected, the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act;

(h) Any other information justifying the exemption or variance;

(i) A statement certifying that, to the best of the petitioner's knowledge and belief, the information provided in the petition includes all information and views on which the petition relies, including representative data, and any information known to the petitioner that is unfavorable to the petition; and

(j) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

§ 1120.144 Referral to the Tobacco Products Scientific Advisory Committee.

FDA may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under § 1120.142. The Tobacco Products Scientific Advisory Committee must report its recommendations to FDA with respect to a petition referred to it within 60 days after the date of the petition's referral.

§ 1120.146 Petition determination.

(a) *Petition for an exemption.* Upon review of the information submitted and any recommendation from the Tobacco Products Scientific Advisory Committee:

(1) FDA may approve the petition for an exemption from a requirement if it determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

(2) FDA may request additional information if necessary to make a determination. FDA may consider the exemption request withdrawn if the information is not received by the time specified in the request.

(b) *Petition for a variance.* Upon review of the information submitted and any recommendation from the Tobacco Products Scientific Advisory Committee:

(1) FDA may approve the petition for a variance if it determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirements in this part are sufficient to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

(2) FDA may request additional information if necessary to make a determination. FDA may consider the variance request withdrawn if the information is not received by the time specified in the request.

(c) *Timeframe.* FDA will either grant or deny the petition within 60 days after:

(1) The date the complete petition was submitted to FDA under § 1120.142; or

(2) The day after FDA referred the petition to the Tobacco Products Scientific Advisory Committee under § 1120.144, whichever is later.

(d) *Order granting a petition for variance.* An order from FDA granting a variance will prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product as may be necessary to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

§ 1120.148 Hearing.

After the issuance of an order under § 1120.146 respecting a petition, the petitioner will have an opportunity for a hearing under part 16 of this chapter.

Dated: February 28, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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